

**FEDERAL FOOD, DRUG,  
AND COSMETIC ACT  
1938—1949**



CFTRI-MYSORE



1078

Federal food dr.



194

194



Time







# FEDERAL FOOD, DRUG, AND COSMETIC ACT

Judicial and Administrative Record  
1938 — 1949

by VINCENT A. KLEINFELD  
and CHARLES WESLEY DUNN



*Published by*

**COMMERCE CLEARING HOUSE, INC.**

PUBLISHERS OF TOPICAL LAW REPORTS

NEW YORK 1

CHICAGO 1

WASHINGTON 4

BOSTON 9

PHILADELPHIA 9

LOS ANGELES 13

SAN FRANCISCO 4



FEDERAL FOOD, DRUG  
AND COSMETIC ACT

Industrial and Administrative Research  
1938 - 1939

1078 ✓

Printed in Canada

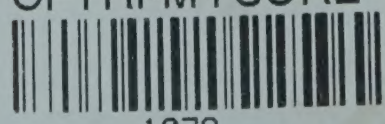
F8, 3: (Z)



F8, 3: (Z)

N49 ← N38

CFTRI-MYSORE



1078

Federal food, dr..



## FOREWORD

An explanation of the purpose, background, and arrangement of this valuable new book on the Federal Food, Drug, and Cosmetic Act appears in Mr. Vincent A. Kleinfeld's excellent introduction. We jointly developed the plan for the book, but Mr. Kleinfeld alone prepared its content. This required great ability, expert knowledge of the Act, and a vast amount of hard work. I deeply appreciate this cooperation by my distinguished colleague, and I am delighted to make a full acknowledgment of it.

Mr. Kleinfeld is highly qualified to prepare this book. He attended the College of the City of New York and the Columbia University School of Law, from which he was graduated in 1929 after being awarded the Robert Noxon Toppan prize in Constitutional Law. He practiced law in New York City for about five years, and in 1935 entered the legal service of the Federal Government, where he has since remained. In that year, he became an Assistant Counsel with the National Recovery Administration. After holding several other Government post, he became associated with the Department of Justice. There he was at first a Special Assistant to the Attorney General and for approximately six years he has been Head of the General Regulations Unit, Criminal Division. He is in general charge of litigation under the Federal Food, Drug, and Cosmetic Act over which the Department of Justice has jurisdiction.

Accordingly, in the pages following there is an authoritative as well as a comprehensive record of the judicial and administrative actions under the Federal Food, Drug, and Cosmetic Act for the period from its enactment in 1938 to May, 1949. This is a reference book needed by all who deal with this Act, and one which has a permanent value to all interested in it.

CHARLES WESLEY DUNN

October 1, 1949







# TABLE OF CONTENTS

	PAGE
Introduction .....	xv
Table of Cases .....	xix
Court Decisions .....	1
Seizure Cases .....	1
Criminal Cases .....	253
Review Cases .....	395
Injunction Cases .....	443
Miscellaneous Cases .....	477
Trade Correspondence .....	561
1 Sulfanilamide and Related Drugs .....	561
2 Aminopyrine and Related Drugs .....	561
3 Cinchophen, Neocinchophen, and Related Drugs .....	562
4 Aminopyrine, Cinchophen, Neocinchophen, Sulfanilamide .....	562
5 Hair Dye Preparations .....	563
6 Eyebrow and Eyelash Dye .....	564
7 Cheese .....	564
8 Corn Meal .....	565
9 Mercury Bleach Cream .....	565
10 Cosmetics .....	566
11 Corn Sugar .....	567
12 Flavoring Extracts .....	568
13 Ovary .....	574
14 Drug Preparations .....	574
15 Egg Substances in Bakery Products .....	578
16 Mineral Oil Coating—Apples .....	579
17 Agar-Agar and Isinglass .....	579
18 Agar-Agar in Candy .....	579
19 Charcoal in Confectionery .....	580
20 Laxatives .....	580
21 Corn Removers and Medical Corn Pads .....	580
22 Declaration of Quantity of Contents .....	580
23 Drug Containers, Quantity of Contents .....	580
24 Depilatories .....	581
25 Ampuls .....	581
26 Deodorant Powder .....	581
27 Titanium Dioxide in Cosmetics .....	581
28 Anchovies, Sprats, Herring Tidbits, Weight of Sauce .....	582
29 Barbituric Acid Derivatives .....	582
30 Artichokes .....	582
31 Alimentary Pastes, Labeling .....	583
32 Antipasto .....	583
33 Blueberries, Huckleberries .....	583
34 Bay Rum .....	584
35 Gum Benzoin, Toxicity of .....	584
36 Barley Sugar, Barley Sugar Candy .....	584
37 Chicory in Bags .....	584
38 Anchovies (Fillets in Olive Oil) .....	585
39 Facial Tissue, Paper Napkins .....	585
40 Baby Oil .....	585
41 Rubber Gloves .....	585
42 Camphor Ice .....	586



## Trade Correspondence—continued

	PAGE
43 Cartons and Lithographed Labels .....	586
44 Citric Acid (Calcium Citrate), Arsenic, Lead .....	586
45 Drug Containers, Labeling .....	587
46 Wording for Ingredient Statement .....	587
47 Goose Liver Paste .....	588
48 Confectionery, Ammonium Carbonate .....	588
49 Chemicals in Foods .....	589
50 Glacial Acetic Acid, Distilled Vinegar .....	589
51 "Pure" on Food Labels .....	589
52 Quantity of Contents Statement Blown in Bottle .....	590
53 Vinegar .....	590
54 Dangerous Drugs—Retail Pharmacists .....	590
55 Rebottling of Bulk Drugs .....	591
56 "Habit Forming" Warnings—Prescriptions .....	591
57 Tomato Juice Added to Standarized "Canned Tomatoes" .....	592
58 Certified Food Colors .....	592
59 Powder Containers—Deceptive Packages .....	592
60 Labeling Statements on Cosmetics in Vanity Cases, etc. ....	593
61 Sunburn Preparations—Sun Tan .....	593
62 Shortenings—Label Declaration of Ingredients .....	594
63 Chewing Gum—Label Declaration of Ingredients .....	595
64 Frozen Desserts—Exemption from Ingredient Statement .....	596
65 Chewing Gum—Ingredients Affecting Plasticity .....	596
66 Non-Alcoholic Carbonated Beverages .....	597
67 Salad Dressing .....	597
68 Declaration of Preservative in Ice Cream .....	598
69 Sherbets and Ices—Declaration of Artificial Color .....	599
70 Ice Cream—Paper Cup Packages .....	599
71 Frozen Foods—Labeling .....	600
72 Ice Cream—Vanillin Flavor .....	600
73 Flavoring Extract Labels .....	600
74 Ice Cream Mix .....	600
75 Vitamin Capsules—Fish Liver Oils and Concentrates .....	601
76 Ergosterol .....	601
77 Condensed Buttermilk .....	602
78 New Drugs .....	602
79 Riboflavin in Milk .....	602
80 "U.S. Grade A" .....	603
81 Raw Materials—Section 405 .....	603
82 Anthelmintics for Animals—Warnings .....	604
83 Drugs Manufactured on Physician's Order .....	604
84 Warnings .....	604
85 Warnings .....	604
86 Sample Packages—Physicians .....	605
87 Process Cheese .....	605
88 "Butter-Nut" .....	605
89 Honey Bread .....	605
90 "Butter Cream Loaf"—"Cream" .....	606
91 Bakery Products—Bread .....	606
92 "Butter Flavored"—"Butter Cookies" .....	607
93 Vitamins .....	607
94 Shortening and Leavening Ingredients .....	607
95 New Drugs .....	608
96 Labeling of Ice Cream Carton .....	608
97 Tea Bags .....	609
98 Tincture of Iodine U.S.P. ....	609
99 Butter—"Fresh" .....	609
100 Tongue Depressors—Wooden Applicators .....	609
101 Shortenings—Lecithin .....	610



	PAGE
102 Hair Dyes—Hydrogen Peroxide—Coal-Tar Colors .....	610
103 Hair Dyes—Coal-Tar Colors .....	610
104 Flavors—"True Fruit" .....	611
105 Supporters—Suspensory Bandages—Wrist Bands .....	611
106 "Vitamin F"—Unsaturated Fatty Acids .....	611
107 "Encapsulating" or "Tablet Compressing" Operations .....	611
108 "Tomato Juice Cocktail"—Chili Sauce .....	612
109 Tooth Brushes—Shaving Brushes .....	612
110 Hot Water Bottle—Syringe .....	613
111 Comb .....	613
112 Razor Blades—Manicuring Instruments .....	613
113 Devices .....	613
114 Rubber Nipples .....	614
115 Yellow Phenolphthalein .....	614
116 Code Labeling—Labeling of Chemicals for Technical Use .....	614
117 "Mercurochrome" .....	615
118 Confectionery—Dried Egg Product .....	615
119 Frozen Desserts—Ingredient Statement .....	616
120 Coal-Tar Color Mixtures for Food Use .....	616
121 Import Procedure .....	617
122 Alcohol—Chloroform .....	617
123 Official Drugs—Exemptions from Listing of Ingredients .....	618
124 Imitation Flavors—"Common or Usual Names" .....	618
125 Lemon Pie or Cake—"Lemon Emulsion" .....	619
126 "Egg Noodles and Chicken"—"Flavoring" .....	619
127 Canned Grapefruit—Label Designations .....	619
128 Surgical Sutures—Use of Certified Color .....	619
129 "Kamala" .....	620
130 Lollipops Containing Aspirin .....	620
131 Absorbent Cotton .....	620
132 Tablet Manufacture—Isopropyl Alcohol .....	620
133 "Bouillon"—"Bouillon Cubes"—"Granulated Chicken Bouillon" .....	621
134 "Tomato Sauce"—"Beans with Pork" .....	621
135 "Lima Beans"—"Butter Beans" .....	622
136 Arsenic—Fluorine—Lead .....	622
137 "Pork and Beans"—Label Arrangement of Ingredient Names .....	623
138 "Mint Tea" .....	623
139 Pyroligneous Acid—"Smoke" .....	623
140 Specially Denatured Alcohol .....	623
141 Dried Beans, Peas and Lentils .....	624
142 Fruit Juices .....	624
143 Pure Fruit Flavors—Use of Fixatives .....	625
144 Caffeine in Soft Drinks Such as "Cola" Beverage .....	625
145 Diglycol Stearate in Food .....	625
164 Soap—Shampoos, Shaving Creams, etc. ....	625
147 "Honey"—Designation as "Peach Blossom" .....	626
148 Coffee—"Java-Mocha Blend" .....	626
149 Egg Albumen—Denaturing for Technical Purposes .....	627
150 Canned Tomatoes—"Solid Pack" .....	627
151 "Imitation Tomato Puree" .....	627
152 Tomato Paste—"Salsa Di Pomodoro" .....	628
153 "Honey and Almond Hand Cream"—"Almond Hand Cream" .....	628
154 Poultry .....	629
155 Poultry—"Milk Fed"—"Retail Package" .....	629
156 Undrawn Poultry—Labeling Requirements .....	629
157 Swiss Cheese—"Sandwich Cuts" .....	630
158 "Home Made" Brand .....	630
159 "Eggs"—Beverage Labeling .....	631
160 Devices, Dangerous Devices, Surgical Instruments .....	631
161 Gelatin Dessert Packages—"Slack-Fill" .....	632



## Trade Correspondence—continued

	PAGE
162 Isopropyl Alcohol in Coal-Tar Mixture .....	632
163 X-Ray Machines .....	633
164 Strophanthus .....	633
165 Dangerous Drugs .....	633
166 Macaroni Products—Noodles—Ingredient Declaration .....	634
167 Artificial Color—"Food Color Added" .....	634
168 Bakery Products—Unwrapped; Cake Fruit Fillers; Nuts .....	634
169 Canned Pinto Beans—"Brown Beauty Beans" .....	635
170 Cosmetics—Cosmetic Ingredients .....	635
171 Flavoring Compounds—Coal-Tar Color .....	636
172 Butter—Use of Neutralizer in Cream .....	636
173 Artificial Flavors .....	636
174 Exemptions for Prescriptions—Physicians .....	637
175 Tomato Products—Artificial Color .....	637
176 Chocolate Flavored with Vanillin .....	638
177 Flavors Containing Vanillin or Ethyl Vanillin .....	638
178 Butter-Labeling .....	638
179 Frozen Swordfish .....	639
180 Lemon, Orange, and Vanilla Non-Alcoholic Flavors .....	639
181 Labeling of Drugs .....	639
182 Coal-Tar Color Certification Procedure .....	640
183 Drugs—Physicians .....	640
184 Tomato Puree—Product not Conforming to Standard .....	640
185 Peanut Butter—Addition of Glycerin .....	641
186 Sulfanilamide .....	641
187 Drugs—Diagnostic Preparations .....	641
188 Digitalis Preparation—Potency Declaration .....	642
189 Drug—List of Active Ingredients .....	642
190 Drugs—"Active Ingredient"—Inert Ingredients .....	642
191 Drug Nomenclature—Titles .....	643
192 "Interstate Commerce"—"Import"—"Export" .....	643
193 Drugs .....	643
194 "Maraschino Cherries" .....	644
195 Soybean Flour—Addition of Carotene .....	645
196 Drugs—Names of "Active Ingredients" .....	645
197 Bakery Products—Individually Wrapped Small Units .....	645
198 Canned Foods—Presence of Nitrogen or Carbon Dioxide .....	646
199 Flour—"Guaranty" Statements .....	646
200 Guaranty Under Act .....	646
201 Saponin—Beverages .....	647
202 Marmalade .....	647
203 Caramel .....	647
204 Food—Fumigant—Methyl Bromide .....	648
205 Canned Foods—Labeling of Round Cans .....	648
206 Importer Distributor—Labeling—Olive Oil .....	649
207 Canned Peaches, Pears, and Apricots—Liquid Packing Medium .....	649
208 Rubbing Alcohol—Isopropyl—Labeling .....	650
209 Potato Chips and Sticks .....	651
210 Caviar .....	651
211 Vignettes on Labels—Salmon Label—Lettuce Leaf .....	652
212 Salad Dressings—Mayonnaise or Chili Sauce—Cereal Starches .....	652
213 Fish Fillets—Sodium Nitrite .....	652
214 Fish Shipped by Fishermen to Wholesalers .....	653
215 "Beverage Base" .....	653
216 Mincemeat—Pie Label—Ingredient Statement .....	654
217 Potatoes in Sacks .....	654
218 Use of Pumpkin in Baked Goods .....	654
219 Flavoring Compounds—Coal-Tar Colors .....	655
220 Hair-Tonics—Tonics .....	655



	PAGE
221 Fruit Flavors—Labeling—Gelatin .....	655
222 Canned Peaches and Similar Fruits .....	656
223 Pectin Preparations—Labeling .....	657
224 Alcoholic Beverages—Beer—Federal Alcohol Administration .....	657
225 “Malt Syrup”—“Malted Cereal Syrup” .....	657
226 Fresh Fruits and Vegetables (Lettuce)—“Box-End” Labels .....	658
227 Sodium Perborate .....	658
228 Use of Color in Tablets (Sodium Bicarbonate) Described in National Formulary .....	659
229 Tooth Powder—“Healthful” on Label .....	659
230 Prunes—Canned “Breakfast Prunes in Syrup” .....	659
231 Narcotics—Hypodermic Tablets in Small Containers .....	659
232 Pretzels—Caustic Lye Dip—Sodium Carbonate .....	660
233 Monosodium Glutamate—Artificial Flavor .....	660
234 Mustard—Labeling .....	660
235 Pickles .....	661
236 Canned Peaches—“Solid Pack Peaches” .....	661
237 Process Cheese—Artificial Color .....	662
238 Confectionery—Resinous Glaze—Shellac, Carnauba Wax, and Stearic Acid .....	662
239 “Silver Dragees”—Confectionery .....	663
240 Confectionery—Assorted Chocolates—Labeling .....	663
241 Candy—Sodium Bisulphite .....	664
242 Confectionery—Cake Decorations .....	664
243 Cosmetics with Perfume .....	665
244 Perfumes—Statement of Quantity .....	665
245 Cuticle Remover .....	665
246 Confectionery—Retail Stores .....	665
247 Canned Field Corn .....	666
248 “Peanut Butter Sandwich” .....	666
249 Shampoo Tints—Hair Dyes .....	666
250 Jurisdiction of Act .....	666
251 Coal-Tar Color Used for Therapeutic Value .....	667
252 Containers—“Shipping Package” .....	667
253 Cosmetic Containers .....	668
254 Distribution by Company Purchasing from Subsidiary—Use of Trade Name .....	668
255 Cane and Maple Syrups—Blends—Invert Sugar .....	669
256 Crabmeat—Added Salt and Citric Acid .....	669
257 Confectionery—Candy Sold by Piece .....	670
258 Fish—Fish Fillets .....	670
259 “Chocolate Ice Cream” .....	671
260 Dental Supplies—Classification .....	671
261 Carbonated Water—Mineral Salts—“Club Soda” .....	672
262 Beverage Base—“Concentrated Orange Juice” .....	672
263 Canned Foods—Mixture of Two Standardized Vegetables .....	672
264 Syrups—“Rock Candy Syrup” .....	673
265 Canned Peas—Artificial Color .....	673
266 Oysters—Use of Tag for Mandatory Labeling .....	673
276 Drugs—Labeling of Derivatives .....	674
268 Drug Nomenclature .....	674
269 Medicinal Soap .....	675
270 Nux Vomica—Strychnine .....	675
271 Raw Sugar .....	675
272 Salt .....	676
273 Blended Edible Oils—Labeling .....	676
274 Containers for Fresh Fruits and Vegetables .....	677
275 Vanilla and Vanillin Flavoring Mixtures—“Imitation Vanilla Flavor” .....	677
276 Process Cheese .....	678



## Trade Correspondence—continued

	PAGE
277 Munster and Tilset Cheeses in Plain Wrappers—Swiss Cheese in Tubs	678
278 Canned Dog Food	679
279 Cottage Cheese—"Creamed Cottage Cheese"	679
280 Drugs—Phrase "Until Relieved" in Directions	680
281 Canned Foods—Use of Term "Fresh"	680
282 Fruits and Vegetables—Wrappers on Individual Items	680
283 "Zucca" Melon—Use in Fruit Cake	680
284 Hexamethylenetetramine—Cod Fish Caviar	681
285 Imitation Flavors	681
286 Chopped Fish in Sausage Casing	681
287 Mineral Oil—Russia	681
288 Feed—Labeling on Sack and Tag	682
289 "Liquid Sugar"	682
290 "Ice Cream Powder"	682
291 Canned Peas—"Telephone"	683
292 "Italian Style Peeled Tomatoes with Added Puree"—Labeling	683
293 "Grenadine"	684
294 Oils—Oleoresins—Official Compendia	684
295 Olive Oil—Labeling—Foreign Language	684
296 Nuts—Labeling	685
297 Chocolate Flavored Malted Milk	685
298 Honey	686
299 Soups—Evaporated Milk—Quantity of Contents Declaration	686
300 Canned Fruits and Vegetables—"Supreme Quality"—"Fancy"	686
301 Drugs—Bromides—Acetanilid	687
302 "Ampuling" and Subsequent Sterilization—Manufacturing	687
303 "No Narcotics or Opiates"—Cathartics	688
304 Common Carriers	688
305 Canned Tomatoes with Tomato Paste	688
306 Simple Analgesic—Minor Pains—Menstruation	689
307 Salad Dressing—Specific Starches	689
308 "Spice Flavorings"	689
309 "Tomato Hot Sauce"—Labeling	690
310 Warnings in Labeling of Drug Products	690
311 Dulcin—Saccharin	691
312 Light Mineral Oil	691
313 Digitalis—Potency—Cat Units	692
314 Ampuls—Labeling	692
315 Vitamin-Carrying Oil—Labeling	692
316 Clinical Thermometers	693
317 Sodium Bisulphite—Confectionery	694
318 Gelatin Dessert Packages—Fill	694
319 Ointment Containing Mercurial Lipoid—Labeling	694
320 Mixture of Distilled and Cider Vinegar	695
321 Canned Peas—Sizes	695
322 Salad Oils—Anti-Oxidants—Mayonnaise	696
323 Agar-Agar—Psyllium Seed—Laxative Warnings	696
324 Drug Products—Listing of Ingredients—Section 201(n)	697
325 Canned Sweet Potatoes—"Yams"	697
326 Dangerous Drugs	698
327 Chlorobutanol	698
328 Cascarin	699
329 Horseradish	699
330 Drugs Dispensed on Physician's Prescription	699
331 Calomel and Soda Tablet, N.F.	700
332 Coal-Tar Color Regulations	700
333 X-Ray Apparatus—Labeling	700
334 Dibutyl Phthalate—Cosmetics	701



	PAGE
335 Certified Coal-Tar Colors .....	701
336 Vegetable Colors—Chlorophyll, etc. ....	702
337 Potassium Iodide .....	702
338 Bromide Preparation—Sea-Sickness, etc. ....	703
339 Canned Pimentos—Seed .....	703
340 Monosodium Glutamate .....	703
341 Process Cheese .....	704
342 Marmalade .....	704
343 Ovarian Substances Administered Orally .....	704
344 "Starch" .....	705
345 Artichokes .....	705
346 Canned Applesauce .....	706
347 Cream .....	706
348 "Diuretic Pills" .....	707
349 Hair Preparations—Quinine—"Tonic" .....	707
350 Dangerous Drugs .....	708
351 Laxative Warnings—Appendicitis .....	709
352 Poultry Feeding—Vitamin D Preparations .....	709
353 Foods Exempt from Ingredient Declaration .....	710
354 Cold Preparations .....	710
355 Calomel Ointments—Venereal Disease .....	711
356 Cinchophen—Neocinchophen .....	711
357 Chlorobutanol .....	712
358 "Imitation Strawberry Jam" .....	712
359 "Pure Food Color" .....	712
360 Aconite Root—Gelsemium—"Laxative Cold Capsules" .....	713
361 Dangerous Drugs .....	713
362 Devices—Labeling .....	714
363 "Vitamin B Complex" .....	715
364 Absorbent Cotton .....	716
365 Alkaloids in Cigarettes .....	716
366 Dangerous Drugs—Veterinary Use .....	716
367 "Antacid"—"Expectorant"—"Diuretic" .....	717
368 Stramonium—Belladonna .....	717
369 Drugs—Exemption .....	718
370 Magnesium Citrate Solution .....	718
371 Mild Mercurial (Blue) Ointment .....	718
372 Arsphenamine—Directions for Use .....	719
373 Sulfanilamide—Veterinary Use .....	719
374 Propylene Glycol .....	720
375 "Prescription Legend—Non-Dangerous Drugs—Liver Preparations" .....	720
376 Glandular Preparations .....	721
377 Monochloroacetic Acid .....	721
378 Menthol Not U.S.P. ....	722
379 Wheat Germ Oil—Vitamin E .....	723
380 Malaria Preparations .....	723
381 Saccharin .....	724
382 Directions for Use .....	724
383 Digitalis Preparations .....	724
384 Dietary Supplement—Nux Vomica .....	725
385 Chlorobutanol .....	725
386 Athlete's Foot—Phenol and Camphor—Caustic Poison Act .....	725
387 Vitamin Capsules and Tablets .....	726
388 Saccharin Tablets .....	726
389 Classification of Drugs Under Section 502(j) .....	727
390 Scabies .....	727
391 Digitalis .....	728
392 Preparations of Cinchona Alkaloids for the Treatment of Malaria .....	728
393 Veterinary Anthelmintics .....	729



## Trade Correspondence—continued

	PAGE
394 Scabies .....	730
395 Salad Dressing—Mineral Oil .....	730
396 Livestock and Poultry Remedies .....	731
397 Venereal Disease—Chemical Prophylactics .....	731
398 Absorbent Cotton .....	732
399 Malaria—Totaquine .....	733
400 Sulfathiazole—Sulfanilamide .....	733
402 Glycols in Cosmetics .....	734
403 Oils in Canned Tuna Fish .....	734
401 Para-Aminobenzoic Acid .....	734
404 Mineral Oil .....	735
405 Sauerkraut with Vinegar .....	736
406 Preserving Powders .....	736
407 Vitamin B <sup>1</sup> Tablets for Use in Enriching Bread .....	737
408 Pyridoxine and Pantothenic Acid in Yeast Tablets .....	738
409 Goods Shipped for Processing, Labeling, or Repacking .....	738
410 Bay Rum with Isopropyl Alcohol .....	738
411 Bakery Products Containing Thiamine, Riboflavin, Niacin, and Iron ..	739
412 Mercurial Preservatives in Cosmetics .....	740
413 Phenol .....	741
414 Sulfonamides .....	741
415 Tonics Containing Strychnine, Iron Salts, and Arsenic .....	741
416 Dried Skim Milk—Public Law 244, 78th Congress .....	742
417 Vitamin D .....	742
418 Epinephrine .....	742
419 Strychnine Tonic .....	743
420 Intravenous Solutions .....	743
421 Rectal Ointments Containing Belladonna or Stramonium .....	743
422 Pills and Tablets Containing Strychnine, Arsenic, etc., with Iron Carbonate .....	744
423 Warning Statements .....	744
424 Directions for Use .....	745
425 Ampuls and Solutions for Injection .....	745
426 Directions for Use .....	746
427 Pineapple Products .....	746
428 Guaranties .....	746
429 Injections .....	747
430 Glandular Preparations .....	747
431 Earache Drops .....	747
1-A Glandular Preparations—Estrogens .....	748
2-A Amino Acids .....	748
3-A DDT in Foods .....	750
4-A Diethylstilbestrol .....	750
5-A Monochloroacetic Acid .....	751
6-A Drugs Dispensed on Prescriptions .....	752
7-A Calcium Compounds .....	752
8-A Mineral Oil Salad Dressings .....	752
<b>Statements of General Policy or Interpretation .....</b>	<b>755</b>
3.1 Notice to Packers of Canned Oysters .....	755
3.2 Notice to Packers and Shippers of Shelled Peanuts .....	756
3.3 Notice to Manufacturers, Packers, and Distributors of Glandular Preparations .....	756
3.4 Notice to Manufacturers, Packers, and Distributors of Drugs for Internal Use Which Contain Mineral Oil .....	757
3.5 Notice to Manufacturers, Packers, and Distributors of Gauze Bandages ..	757
3.6 Notice to Importers of Peruvian Canned Fish, Peruvian Canned Bonita, and Tuna .....	758



3.7 Notice to Manufacturers, Packers, and Distributors of Veterinary Preparations and Animal Feeds .....	759
3.8 Notice to Manufacturers, Packers, and Distributors of Penicillin-Containing Drugs for Veterinary Use .....	759
3.9 Notice to Manufacturers, Packers, and Distributors of Salt Substitutes ..	762
3.10 Notice to Manufacturers and Users in Food Products of Monosodium Glutamate .....	762
<b>Table of References from Law to Interpretations .....</b>	<b>763</b>
<b>The Federal Food, Drug, and Cosmetic Act .....</b>	<b>825</b>
Chapter I—Short Title .....	825
Section 1 Short Title .....	825
Chapter II—Definitions .....	825
Section 201 Definitions .....	825
Chapter III—Prohibited Acts and Penalties .....	826
Section 301 Prohibited Acts .....	826
Section 302 Injunction Proceedings .....	827
Section 303 Penalties .....	827
Section 304 Seizure .....	828
Section 305 Hearing Before Report of Criminal Violation .....	829
Section 306 Report of Minor Violations .....	829
Section 307 Proceedings in Name of United States; Provisions as to Subpoenas .....	829
Chapter IV—Food .....	830
Section 401 Definitions and Standards for Food .....	830
Section 402 Adulterated Food .....	830
Section 403 Misbranded Food .....	831
Section 404 Emergency Permit Control .....	831
Section 405 Regulations Making Exemptions .....	832
Section 406 Tolerances for Poisonous Ingredients in Food and Certification of Coal-Tar Colors for Food .....	832
Chapter V—Drugs and Devices .....	833
Section 501 Adulterated Drugs and Devices .....	833
Section 502 Misbranded Drugs and Devices .....	833
Section 503 Exemptions in Case of Drugs and Devices .....	835
Section 504 Certification of Coal-Tar Colors for Drugs .....	835
Section 505 New Drugs .....	835
Section 506 Certification of Drugs Containing Insulin .....	837
Section 507 Certification of Drugs Containing Penicillin, Streptomycin, Aureomycin, Chloramphenicol, or Bacitracin .....	837
Chapter VI—Cosmetics .....	838
Section 601 Adulterated Cosmetics .....	838
Section 602 Misbranded Cosmetics .....	839
Section 603 Regulations Making Exemptions .....	839
Section 604 Certification of Coal-Tar Colors for Cosmetics .....	839
Chapter VII—General Administration Provisions .....	839
Section 701 Regulations and Hearings .....	839
Section 702 Examinations and Investigations .....	841
Section 702A Sea-Food Inspection .....	841
Section 703 Records of Interstate Shipment .....	841
Section 704 Factory Inspection .....	842
Section 705 Publicity .....	842
Section 706 Cost of Certification of Coal-Tar Colors .....	842
Chapter VIII—Imports and Exports .....	842
Section 801 .....	842
Chapter IX—Miscellaneous .....	843
Section 901 Separability Clause .....	843
Section 902 Effective Date and Repeals .....	843



	PAGE
The Postponement Act .....	845
The Butter Act .....	846
The Wrapped Meats Act .....	847
The Skim Milk Act .....	848
Forms .....	849
Claim .....	849
Consent Decree of Condemnation Permitting Salvaging of Product .....	850
Bond Furnished Pursuant to Decree Permitting Salvaging .....	853
Petition for Exoneration of, and Form of Order Exonerating, Bond .....	854
Answer Admitting Allegations of Libel and Petitioning for Release of Product for Salvaging .....	856
Order Accelerating Return of Monition, etc. ....	857
Answer .....	858
Order Permitting Withdrawal of Claim and Answer .....	859
Motion to Vacate Decree Entered On Default and Order Opening Default .....	861
Stipulation and Order Consolidating and Removing Seizure Action .....	864
Interrogatories .....	866
Consent Decree of Injunction and Related Papers .....	867
Index .....	871

---



## INTRODUCTION

The passage of the Federal Food, Drug, and Cosmetic Act was an onerous task. Despite the many inadequacies of the Food and Drugs Act of 1906, it was a Herculaean undertaking, indeed, to persuade Congress to enact a law which would be adequate for the protection of the consuming public under present-day economic conditions and yet not cause undue hardship to the affected industries. Of necessity, therefore, the 1938 Act represented a series of compromises, and some minor defeats for those who had vigorously advocated a sound and strong law for the protection not only of the consumer but of the great majority of manufacturers and distributors of food, drugs, and cosmetics as well. By the vesting of jurisdiction over advertising in the Federal Trade Commission, a serious blow was dealt to those who believed that it was most inefficient and inadvisable that jurisdiction, insofar as "labeling" was concerned, should be in the hands of one federal agency, and jurisdiction, insofar as "advertising" was concerned, should be vested in another. Staunch proponents of a comprehensive law particularly felt this to be true because of their belief that advertising is essentially an extension of the label, and that governmental agencies handling virtually the same problem are destined to have more than their aliquot share of strife and stress.

Many earnest consumer groups feared that the series of compromises which culminated in the 1938 Act had resulted in an emasculated bill which was totally inadequate to cope with current problems. Ten years' experience since the enactment of the Federal Food, Drug, and Cosmetic Act reveals most clearly, however, that the law is a strong and zealous defender of the public weal. Three major considerations have helped bring this about. The first is the extremely liberal manner in which the courts, particularly the higher courts, have interpreted the Act. A careful study of the legislative history of the statute indicates that it was doubtful that many of even the most diligent proponents of the passage of a strong law comprehended the manner in which many of the provisions of the Act have been construed. No one can help but be at least slightly surprised at decisions of such far-reaching scope as *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, *United States v. Dotterweich*, 320 U.S. 277, *United States v. Walsh*, 331 U.S. 432, *United States v. Olsen*, 161 F. 2d 669 (CCA—9), certiorari denied, 332 U.S. 768, *United States v. Two Bags \* \* \* Poppy Seeds*, 147 F. 2d 123 (CCA—6), and such recent cases of fundamental importance as *United States v. Sullivan*, 332 U.S. 689, *Kordel v. United States*, 335 U.S. 345, and *United States v. Urbeteit*, 335 U.S. 355.



The second factor in making the Act as potent a weapon as it is in the field of food, drugs, and cosmetics is the extraordinary vigilant yet level-headed manner in which the statute has been administered by the Food and Drug Administration. The result has been the creation of an attitude of real respect towards and confidence in the Administration on the part of the Congress, the courts, the affected industries, the press, and the consuming public.

The third consideration is a realization by the greater segments of the regulated industries that the Act protects not merely the housewife, and her family and pocketbook, but also the ordinary, typical manufacturer or distributor who is attempting to bring before the public safe, wholesome, and honestly labeled products, thus building invaluable good will and undoubtedly thereby increasing financial returns.

The provisions of the Federal Food, Drug, and Cosmetic Act, therefore as construed by the courts and administered by the Food and Drug Administration, have a most important bearing on the tremendous food, drug, and cosmetic industries of the nation. The field covered by the statute was considerably augmented by the decisions of the Supreme Court in the *Sullivan*, *Kordel*, and *Urbeteit* cases and the passage of the Miller Bill, Public Law 749, 80th Congress.

There is no question but that the *Sullivan* decision, the language of the opinion rendered by the Supreme Court in that case, and the clear and explicit language and legislative history of the Miller Amendment, bring within the scope of the Federal Food, Drug, and Cosmetic Act practically every establishment in the country, retail or otherwise, dealing with food, drugs, and cosmetics. Every corner restaurant, drug store, grocery store, and beauty parlor which may have on its shelves or in its cupboards a product which at one time in the past crossed a state line is clearly within the purview of the statute.

Even as far as advertising is concerned (direct jurisdiction over which was vested in the Federal Trade Commission by the Wheeler-Lea Act), the construction given by the Supreme Court in the *Kordel* and *Urbeteit* cases to the term "labeling," as defined in Section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m)), brings within the grasp of the statute many items which are normally considered advertising media. In addition, the construction placed upon Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1)) by the Food and Drug Administration indirectly places advertising of drug products and devices within the coverage of the statute. Thus, the regulation issued by the Administration under the Section 21 CFR, 1946 Supp., §2.106) declares that directions for use may be inadequate by reason, among others, of omission, in whole or in part, or incorrect specifica-



tion, of directions for use in all conditions for which the drug or device is prescribed, recommended, or suggested in its labeling, or in advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or distributor, or in such other conditions, if any there be, for which the drug or device is commonly and effectively used. This administrative construction has been upheld by several district courts. If such directions are placed in the labeling, and the drug or device is not effective in the cure or treatment of the diseases specified in the directions, a charge under Section 502(a) of the Act (21 U.S.C. 352(a)) will then probably lie. Further, the administrative viewpoint, likewise sustained by a number of district courts, is that a drug or device is misbranded under Section 502(f)(1) unless its labeling specifies the names of the diseases for which it is marketed—and that such ailments can be gathered by a perusal of the advertising. Again, if the names of the diseases are forced into the labeling by Section 502(f)(1), and the article is not in fact efficacious in their treatment, a Section 502(a) charge will lie.

The increasing importance of the field, therefore, impelled the authors to prepare a work which is neither a text nor a mere compilation. The design was to furnish a useful guide and source book not only for the attorney, both expert and nonexpert, in the field, but also for the administrative official who would like to have on his desk something for ready reference.

Essentially, the book is divided into three portions. One part contains every opinion rendered under the Federal Food, Drug, and Cosmetic Act which appears in the jurisdictional law reporters, and, in addition, various so-called "unpublished" decisions, which cannot be found except perhaps in notices of judgment published by the Food and Drug Administration and in the CCH FOOD DRUG COSMETIC LAW REPORTS. Each opinion has been digested, and the digests contain references to the various subsections of the Act to which each portion of the digest applies. It is believed that the assembly of all the decisions rendered under the 1938 Act in one place should prove a great convenience to persons interested in the field.

The second portion of the book contains all of the "Trade Correspondence" and "Statements of General Policy or Interpretation" issued by the Food and Drug Administration. These are, of course, day-by-day informal announcements and answers by the Administration on current problems, and the opinions expressed in them necessarily change from time to time as more experience and data are gathered and interpretations of the statutory provisions are made by the courts. Nevertheless, they are not only interesting but illuminating in attempting to find a solution to many problems and in tracing the attitude of



the Food and Drug Administration with respect thereto. These also are preceded by brief digests, and it is believed that the close association in one volume of all of the administrative pronouncements, together with the judicial opinions, will be helpful not only to attorneys in the field but also to non-lawyers who would like to have at their finger-tips both the judicial and administrative interpretations of the statute.

The third major part of the book represents an attempt to furnish exhaustive references to the pertinent material when any problem arises under any section of the Act. In this portion, there have been listed under each subsection of the statute (1) references to the applicable regulations promulgated by the Food and Drug Administration, (2) citations to all relevant cases decided under the Food and Drugs Act of 1906, (3) citations to the decisions, as indicated above, rendered under the Federal Food, Drug, and Cosmetic Act, (4) citations to pertinent decisions rendered by the courts under the Federal Trade Commission Act, (5) citations to pertinent opinions of the Attorney General of the United States, and (6) citations to the Trade Correspondence and Statements of General Policy or Interpretation which deal with the subsection. Thus, in the event a question presents itself with respect to any particular subsection of the statute, this portion of the book is designed to furnish a lead to all relevant material bearing on or dealing with the subsection.

Lastly, an attempt has been made to furnish an exhaustive and comprehensive index for ready reference by both lawyers and laymen.

In the preparation of this book, textual material in the publisher's FOOD DRUG COSMETIC LAW REPORTS was freely drawn upon.

The authors wish to express their appreciation for the assistance rendered by the Food and Drug Administration, and by Edward E. Turkel and Bernard D. Levinson of the General Counsel's Office of the Federal Security Agency.

VINCENT A. KLEINFELD

October 1, 1949

---



# TABLE OF CASES

xix

## A

	PAGE
Alberty; United States v. 65 F. Supp. 945 (S.D. Calif., 1946)	315
reversed, 159 F. 2d 278 (C.C.A. 9, 1947)	332
American Lecithin Co., Inc. v. McNutt 155 F. 2d 784 (C.C.A. 2, 1946) certiorari denied 329 U.S. 763 (1946)	438
Arner Co., Inc. et al. v. United States 142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)	99

## B

Barnes et al. v. United States 142 F. 2d 648 (C.C.A. 9, 1944)	285
Bowman v. Retzlaff et al. (The James J. Hill) 65 F. Supp. 265 (D. Md., 1946)	496
Buffalo Pharmacal Co., Inc. et al.; United States v. 131 F. 2d 500 (C.C.A. 2, 1942)	262
Byrd v. United States 154 F. 2d 62 (C.C.A. 5, 1946)	177

## C

C. C. Co. v. United States 147 F. 2d 820 (C.C.A. 5, 1945)	129
Cataldo; United States v. 157 F. 2d 802 (C.C.A. 1, 1946)	193
Collier, etc. v. McNutt et al. (D. of Col., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 2140) Issued April 1948	493
Columbia Cheese Co. et al v. McNutt 137 F. 2d 576 (C.C.A. 2, 1943), certiorari denied 321 U.S. 777 (1944)	426
Commercial Creamery Co.; United States v. 43 F. Supp. 714 (E. D. Wash., 1942)	257
Commonwealth Brewing Corporation and Leo Kaufman; United States v. (D. Mass., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7926) Issued March 1946	310
Cook Chocolate Co. v. Miller et al 72 F. Supp. 573 (D. of Col., 1947)	509
Corrao, Antonio; United States v. (E.D. N.Y., 1948)	387
Coughlin, Martin (Diamonex Co.) v. Federal Security Administrator (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of Orders Under Sections 701(f) and 505(h) of the Federal Food Drug, and Cosmetic Act (No. 7) Issued July 1946	436
Cowley Pharmaceuticals, Inc.; United States v. (D. Mass., 1948)	473
Crescent-Kelvan Company et al.; United States v. 164 F. 2d 582 (C.C.A. 3, 1948)	359
Crown Rubber Sundries Co. et al.; United States v. 67 F. Supp. 92 (N.D. Ohio, 1946)	330

## D

Dailey, Elmer J. (Dailey's Laboratories); United States v. (S.D. Calif., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1326) Issued November 1945	299
Dean Rubber Mfg. Co. et al.; United States v. 71 F. Supp. 96 (W.D. Mo., 1946)	466
72 F. Supp. 819 (W.D. Mo., 1947)	471
Diamonex Co. (Martin Coughlin) v. Federal Security Administrator (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug, and Cosmetic Act (No. 7) Issued July 1946	436
Dotterweich; United States v. 320 U.S. 277 (1943)	278
Douglas; United States v. 155 F. 2d 894 (C.C.A. 7, 1946)	318



## E

## PAGE

Eight Hundred and Ninety-Three One-Gallon Cans * * * "Brown's Inhal-ent"; United States v. 45 F. Supp. 467 (D. Del., 1942) .....	26
Eighteen Hundred and Fifty-One Cartons * * * Whiting Frosted Fish et al.; United States v. 55 F. Supp. 343 (D. Colo., 1944) .....	110
reversed, 146 F. 2d 760 (C.C.A. 10, 1945) .....	134
Eighty-Eight Cases * * * "Bireley's Orange Beverage"; United States v. 5 F.R.D. 503 (D. N.J., 1946) .....	501
Eleven and One-Fourth Dozen Packages * * * "Mrs. Moffat's Shoo Fly Powders for Drunkenness"; United States v. 40 F. Supp. 208 (W.D. N.Y., 1941) .....	8
Empire Oil & Gas Corporation et al. v. United States 136 F. 2d 868 (C.C.A. 9, 1943) .....	270

## F

Federal Security Administrator v. Quaker Oats Co. 318 U.S. 218 (1943) .....	419
Fifteen Cartons Sekov Reducer; United States v. (S.D. Tex., 1941) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1002) Issued March 1945 .....	12
45 F. Supp. 52 (S.D. Tex., 1942) .....	22
Fifty and Three-Fourths Dozen Bottles, More or Less, of "Sulfa-Seb," et al.; United States v. 54 F. Supp. 759 (W.D. Mo., 1944) .....	94
Fifty-Five Cases Popped Corn et al.; United States v. 62 F. Supp. 843 (D. Idaho, 1943) .....	56
Five Barrels Dried Whole Eggs; United States v. 53 F. Supp. 652 (E.D. Wis., 1943) .....	59
Five Cases * * * "Capon Springs Water"; United States v. 62 F. Supp. 736 (S.D. N.Y., 1945) .....	141
reversed, 156 F. 2d 493 (C.C.A. 2, 1946) .....	187
Five Cases * * * "Figlia Mia Brand * * * " et al.; United States v. (D. Conn., 1949) .....	521
Forty-Five and Two-Thirds Dozen Packages * * * "U-X Improved Shaving Medium"; United States v. 46 F. Supp. 112 (S.D. N.Y., 1942) .....	25
Forty-Seven Barrels Dried Whole Eggs; United States v. 53 F. Supp. 652 (E.D. Wis., 1943) .....	59
Forty-Three and One-Half Gross * * * "Xcello's Phrophylactics," et al.; United States v. 65 F. Supp. 534 (D. Minn., 1946) .....	173
Fourteen Cartons * * * "Ayd's Candy * * *"; United States v. (E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug and Cosmetic Act, Foods (No. 2862) Issued February 1949 .....	182
Fresh Grown Preserve Corporation v. United States 143 F. 2d 191 (C.C.A. 6, 1944) .....	484
Fresh Grown Preserves Corp. et al. v. United States 144 F. 2d 136 (C.C.A. 4, 1944) .....	490

## G

Gellman et al. v. United States 159 F. 2d 881 (C.C.A. 8, 1947) .....	205
Gerber Products Co.; United States v. (W.D. Mich., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7808) Issued January 1946 ..	306
Ghadiali, Dinshah P., and Dinshah Spectro-Chrome Institute ; United States v. 165 F. 2d 957 (C.C.A. 3, 1948), certiorari denied 334 U.S. 821 (1948) ..	365
Gray, Lafayette M., v. United States (C.A. 8, 1949) .....	537
Greenbaum; United States v. 138 F. 2d 437 (C.C.A. 3, 1943), 152 A.L.R. 751 .....	275



# Table of Cases

xxi

H	PAGE
Hain, Harold (Hain Pure Food Co.); United States v. (S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944 .....	265
Helco Products Co., Inc. v. McNutt et al. 137 F. 2d 681 (App. D.C., 1943) .....	477
Heron, Norman C.; United States v. (S.D. Calif., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 345) Issued March 1942 .....	253
Hill, The James J. (Bowman v. Retzlaff et al.) 65 F. Supp. 265 (D. Md., 1946) .....	496
Howard-Iowa Products Co.; United States v. (S.D. Iowa, 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1010) Issued March 1945 .....	274
Hygrade Food Products Corporation v. United States 160 F. 2d 816 (C.C.A. 8, 1947) .....	468
I	
In re United States 140 F. 2d 19 (C.C.A. 5, 1943) .....	480
J	
Joseph v. United States 145 F. 2d 74 (C.C.A. 9, 1944), certiorari denied 323 U.S. 776 (1944) .....	303
K	
Kaadt, Dr. Charles, and Dr. Peter S.; United States v. 171 F. 2d 600 (C.A. 7, 1948) .....	388
Kent Food Corp. and Clark-Iger Food Products Co., Inc.; United States v. 168 F. 2d 632 (C.C.A. 2, 1948), certiorari denied 335 U.S. 885 (1948) .....	242
Kordel; United States v. 66 F. Supp. 538 (N.D. Ill., 1946) .....	328
affirmed, 164 F. 2d 913 (C.C.A. 7, 1947) .....	343
affirmed, 335 U.S. 345 (1948) .....	382
L	
Land O'Lakes Creameries, Inc., et al. v. McNutt et al 132 F. 2d 653 (C.C.A. 8, 1943) .....	412
Lazere; United States v. 56 F. Supp. 730 (N.D. Iowa, 1944) .....	451
Lee, etc.; United States v. 40 F. Supp. 801 (E.D. Wis., 1941) .....	443
reversed, 131 F. 2d 464 (C.C.A. 7, 1942) .....	445
Levine, Bess J., Trading as Miracle Food Co.; United States v. (E.D. Pa., 1948) .....	367
Libby, McNeill & Libby v. United States 148 F. 2d 71 (C.C.A. 2, 1945) .....	145
Lord-Mott Co., Inc.; United States v. 57 F. Supp. 128 (D. Md., 1944) .....	289
M	
Manning v. United States 161 F. 2d 827 (C.C.A. 5, 1947) .....	507
Marshall Kirby & Co., Inc.; United States v. 141 F. 2d 767 (C.C.A. 7, 1944) .....	85
Martin Coughlin (Diamonex Co.) v. Federal Security Administrator (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug, and Cosmetic Act (No. 7) Issued July 1946 .....	436
Maryland Baking Company and Sara Piem, an individual; United States v. 81 F. Supp. 560 (N.D. Ga., 1948) .....	379
N	
Nine Bottles * * * "Colusa Natural Oil," etc. (Colusa Remedy Co., Intervenor); United States v. 78 F. Supp. 721 (N.D. Iowa, 1947) .....	218



Nine Hundred and Ninety-Eight Cases of Tomato Puree; United States v. (W.D. Mich., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7850) Issued January 1946 ..	28
Nine Hundred and Thirty-Five Cases * * * Tomato Puree; United States v. 136 F. 2d 523 (C.C.A. 6, 1943), certiorari denied 320 U.S. 778 (1943) 65 F. Supp. 503 (N.D. Ohio, 1946) .....	44 179
Nine Hundred and Two Cases * * * "Michigan Brand Grade A Tomato Catsup * * *"; United States v. (E.D. N.Y., 1947) .....	513
Ninety-Nine Cases * * * Peach Fountain Fruit, etc.; United States v. (E.D. Tenn., 1948) .....	245

## O

Obrecht, G. Fred, et al.; United States v. (D. Md., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8894) Issued February 1947 .....	456
Olsen; United States v. 161 F. 2d 669 (C.C.A. 9, 1947), certiorari denied 332 U.S. 768 (1947) ..	210
One Article of Device Labeled Spectro-Chrome et al.; United States v. 66 F. Supp. 754 (D. Ore., 1946) .....	207
77 F. Supp. 50 (D. Ore., 1948) order of seizure .....	226
One Device, etc., "Tox Eliminator," etc.; United States v. 160 F. 2d 194 (C.C.A. 10, 1947) .....	199
One Dozen Bottles * * * "Bonquet Tablets"; United States v. 146 F. 2d 361 (C.C.A. 4, 1944) .....	122
One Hundred and Eight Boxes of Cheddar Cheese; United States v. (S.D. Iowa, 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 5478) Issued January 1945 ..	33
One Hundred and Eighty-Four Barrels Dried Whole Eggs; United States v. 53 F. Supp. 652 (E.D. Wis., 1943) .....	59
One Hundred and Forty-Nine Gift Packages; United States v. 52 F. Supp. 993 (E.D. N.Y., 1943) .....	54
One Hundred and Forty-Three Packages * * * Nue-Ovo; United States v. 51 F. Supp. 1 (W.D. Wash., 1943) .....	50
One Hundred and Four Cases * * * "Colorado Gold Brand Creamery Butter * * *"; United States v. (S.D. Calif., 1949) .....	526
One Hundred and Sixteen Boxes * * * "Arden Assorted Candy Drops," etc.; United States v. 80 F. Supp. 911 (D. Mass., 1948) .....	247
One Thousand, Eight Hundred and Fifty-One Cartons * * * Whiting Frosted Fish et al.; United States v. 55 F. Supp. 343 (D. Colo., 1944) .....	110
reversed, 146 F. 2d 760 (C.C.A. 10, 1945) .....	134
One Thousand, Three Hundred and Seventy-Five Cases of Tomato Paste; United States v. (D. Conn., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 3761) Issued May 1943 ....	13
One Thousand, Three Hundred and Twenty-Two Cans * * * Black Raspberry Puree; United States v. 68 F. Supp. 881 (N.D. Ohio, 1946) .....	195
One Thousand, Two Hundred and Thirty-Two Cases * * * American Beauty Brand Oysters; United States v. 43 F. Supp. 749 (W.D. Mo., 1942) .....	18

## P

* Paddock; United States v. 67 F. Supp. 819 (W.D. Mo., 1946) .....	462
68 F. Supp. 407 (W.D. Mo., 1946) .....	463
Parfait Powder Puff Co., Inc.; United States v. 163 F. 2d 1008 (C.C.A. 7, 1947), certiorari denied 332 U.S. 851 (1948) .....	341
Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States 169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)	370
Phelps Dodge Mercantile Co.; United States v. 157 F. 2d 453 (C.C.A. 9, 1946), certiorari denied 330 U.S. 818 (1947)	189



## Table of Cases

xxiii

PAGE

- Pinaud, Inc.; United States v.  
(S.D. N.Y., 1947) Notices of Judgment Under the Federal Food,  
Drug, and Cosmetic Act, Cosmetics (No. 152) Issued February 1949 526

## Q

- Quaker Oats Co. v. Federal Security Administrator  
129 F. 2d 76 (C.C.A. 7, 1942) 405

## R

- Research Laboratories, Inc.; United States v.  
126 F. 2d 42 (C.C.A. 9, 1942), certiorari denied 317 U.S. 656 (1942) 15  
Research Laboratories, Inc. v. Robert E. Hannegan et al.  
(D. of Col., 1947) 514  
Research Laboratories, Inc. v. United States  
167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948) 227  
Roma Macaroni Factory et al.; United States v.  
75 F. Supp. 663 (N.D. Calif., 1947) 348  
Royal Lee, etc.; United States v.  
40 F. Supp. 801 (E.D. Wis., 1941) 443  
reversed, 131 F. 2d 464 (C.C.A. 7, 1942) 445  
Rubenstein v. United States  
153 F. 2d 127 (App. D.C., 1946) 460  
Runkle Co., et al.; United States v.  
(N.D. Ohio, 1948) 475

## S

- Salamonie Packing Company v. United States  
165 F. 2d 205 (C.C.A. 8, 1948), certiorari denied 333 U.S. 863 (1948) 225  
Saunders Mills, Inc., Clarence M. Saunders, and Evelyn M. Crow; United  
States v.  
(S.D. Ohio, 1944) Notices of Judgment Under the Federal Food,  
Drug, and Cosmetic Act, Foods (No. 8587) Issued July 1946 454  
Sekov Corporation and Hazel Ruth Vokes (Sekov Studios); United States v.  
(S.D. Calif. 1943) Notices of Judgment Under the Federal Food,  
Drug, and Cosmetic Act, Drugs and Devices (No. 1001) Issued  
March 1945 448  
Sekov Corporation v. United States  
139 F. 2d 197 (C.C.A. 5, 1943) 53  
Seven Barrels, etc., "Spray Dried Whole Egg"; United States v.  
141 F. 2d 767 (C.C.A. 7, 1944) 85  
Seven Hundred and Thirty-Eight Cases \* \* \* "Jiffy-Lou Vanilla Flavor  
Pudding"; United States v.  
71 F. Supp. 279 (D. Ariz., 1946) 171  
Seven Hundred and Twenty Bottles \* \* \* Plantation Pure Vanilla Extract,  
etc.; United States v.  
3 F.R.D. 466 (E.D. N.Y., 1944) 482  
Seven Jugs, etc., "Dr. Salsbury's Rakos," etc.; United States v.  
53 F. Supp. 746 (D. Minn., 1944) 64  
Seventy and One-Half Dozen Bottles \* \* \* "666"; United States v.  
(M.D. Ga., 1944) Notices of Judgment Under the Federal Food,  
Drug, and Cosmetic Act, Drugs and Devices (No. 1231) Issued  
June 1945 89  
Seventy-Five Cases \* \* \* Peanut Butter, etc.; United States v.  
54 F. Supp. 641 (D. Md., 1944) 82  
reversed, 146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S.  
856 (1945) 126  
Seventy-Four Cases \* \* \* "C.C. Brand Oysters"; United States v.  
55 F. Supp. 745 (W.D. S.C., 1944) 119  
Seventy-Four Cases \* \* \* Plum Jelly et al.; United States v.  
73 F. Supp. 1009 (D. Minn., 1947) 511  
Six Devices, "Electreat Mechanical Heart"; United States v.  
38 F. Supp. 236 (W.D. Mo., 1941) 5  
Six Dozen Bottles \* \* \* "Dr. Peter's Kuriko"; United States v.  
55 F. Supp. 458 (E.D. Wis., 1944) 118  
158 F. 2d 667 (C.C.A. 7, 1947) 197  
Six Hundred Units \* \* \* "Nue-Ovo," etc.; United States v.  
60 F. Supp. 144 (W.D. Mo., 1945) 154



Six Hundred and Fifty Bags of Roasted Malted Cereal et al.; United States v. (W.D. Mo., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 6403) Issued June 1945 . . . .	51
Six Hundred and Sixty-Seven Cases of Canned Herring Roe; United States v. (D. Md., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8917) Issued February 1947	30
Sixteen Cans, etc., "Dr. Salisbury's Phen-O-Sal Tablets," etc.; United States v. 53 F. Supp. 746 (D. Minn., 1944) . . . . .	64
Sixty-Seven Bottles, etc., "Dr. Salisbury's Can-Pho-Sal," etc.; United States v. 53 F. Supp. 746 (D. Minn., 1944) . . . . .	64
Sixty-Two Packages * * * Marmola Prescription Tablets et al.; United States v. 48 F. Supp. 878 (W.D. Wis., 1943) . . . . .	34
affirmed, 142 F. 2d 107 (C.C.A. 7, 1944), certiorari denied 323 U.S. 731 (1944) . . . . .	107
Smith v. Great Atlantic & Pacific Tea Co. 170 F. 2d 474 (C.A. 8, 1948) . . . . .	514
Staley Mfg. Co., A.E., v. Secretary of Agriculture et al. 120 F. 2d 258 (C.C.A. 7, 1941) . . . . .	395
Stinson Canning Co. et al. v. United States 170 F. 2d 764 (C.A. 4, 1948), certiorari denied 336 U.S. 951 (1949) . .	518
Sullivan; United States v. 67 F. Supp. 192 (M.D. Ga., 1946) . . . . .	319
reversed, 161 F. 2d 629 (C.C.A. 5, 1947) . . . . .	334
reversed, 332 U.S. 689 (1948) . . . . .	350
Swift & Co. et al.; United States v. 53 F. Supp. 1018 (M.D. Ga., 1943) . . . . .	449

## T

Thirteen Hundred and Seventy-Five Cases of Tomato Paste; United States v. (D. Conn., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 3761) Issued May 1943 . . . . .	13
Thirteen Hundred and Twenty-Two Cans * * * Black Raspberry Puree; United States v. 68 F. Supp. 881 (N.D. Ohio, 1946) . . . . .	195
Thirty-Six Drums of Pop'n Oil; United States v. 164 F. 2d 250 (C.C.A. 5, 1947) . . . . .	215
Thirty-Two and One-Half Cases of Merlek Mineral Water; United States v. (D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942 . . . . .	2
Three and Seven-Twelfths Dozen Packages of Nu-Charme Perfected Brow Tint; United States v. 59 F. Supp. 284 (W.D. La., 1945) . . . . .	149
61 F. Supp. 847 (W.D. La., 1945) . . . . .	159
61 F. Supp. 850 (W.D. La., 1945) . . . . .	161
Three Hundred Cans, etc., of Black Raspberries, et al.; United States v. 7 F.R.D. 36 (N.D. Ohio, 1946) . . . . .	505
Three Hundred and Seventy-Nine Bottles * * * of Grayvita; United States v. (N.D. Ill., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7905) Issued January 1946 . .	58
Three Hundred and Seventy-Six Dozen Small Size, etc., Emerson's Bromo Seltzer; United States v. (S.D. N.Y., 1939) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 81) Issued May 1940 . . . . .	1
Three Hundred and Six Cases * * * "Sandford Tomato Catsup With Preservative"; United States v. 55 F. Supp. 725 (E.D. N.Y., 1944) . . . . .	115
Three Hundred and Thirty-Eight Cartons, More or Less, of Butter et al. v. United States 165 F. 2d 728 (C.C.A. 4, 1947) . . . . .	222



	PAGE
Three Unlabeled 25-Pound Bags Dried Mushrooms et al.; United States v. 157 F. 2d 722 (C.C.A. 7, 1946) .....	191
Triangle Candy Co. et al. v. United States 144 F. 2d 195 (C.C.A. 9, 1944), 155 A.L.R. 903 .....	294
Twelve Bottles of Esterex; United States v. (E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949	523
Twelve Hundred and Thirty-Two Cases * * * American Beauty Brand Oysters; United States v. 43 F. Supp. 749 (W.D. Mo., 1942) .....	18
Twenty Cases, etc., of Jello Vanilla Flavor Pudding; United States v. 77 F. Supp. 231 (S.D. N.Y., 1947) .....	212
Twenty-Four Cans, etc., Butter et al.; United States v. 148 F. 2d 365 (C.C.A. 5, 1945), certiorari denied 326 U.S. 752 (1945)	156
Twenty-Nine Bottles * * * "Ocean-Lax," etc.; United States v. 44 F. Supp. 317 (E.D. Pa., 1942) .....	21
Twenty-Six Cartons Nu-Charme Perfected Brow Tint; United States v. 59 F. Supp. 284 (W.D. La., 1945) .....	149
61 F. Supp. 847 (W.D. La., 1945) .....	159
61 F. Supp. 850 (W.D. La., 1945) .....	161
Twenty-Six Dozen Bottles, etc., "Wheatamin Brand Cevigards"; United States v. 60 F. Supp. 626 (W.D. Mich., 1945) .....	154
Twenty-Six Hundred and Forty Cases of Dried Prunes; United States v. (W.D. N.C., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7277) Issued September 1945	122
Twin City Milk Producers Ass'n et al. v. McNutt et al 122 F. 2d 564 (C.C.A. 8, 1941) .....	398
123 F. 2d 396 (C.C.A. 8, 1941) .....	403
Two Articles of Device * * * "Tox Eliminator," etc.; United States v. (E.D. Okla., 1949) .....	529
Two Bags * * * Poppy Seeds; United States v. 54 F. Supp. 706 (N.D. Ohio, 1944) .....	78
reversed, 147 F. 2d 123 (C.C.A. 6, 1945) .....	135
Two Hundred and Eighty-Four Barrels of Dried Eggs, etc.; United States of America v. 52 F. Supp. 661 (W.D. Tenn., 1943) .....	48
Two Hundred and Fifteen Cases * * * "Michigan Brand Grade A Tomato Catsup * * *"; United States v. (E.D. N.Y., 1947) .....	513
Two Hundred and Fifty-Four Cases * * * "Baby Brand Tomato Sauce," etc.; United States v. 63 F. Supp. 916 (E.D. Ark., 1945) .....	162
Two Hundred and Thirty Boxes, More or Less, of Fish et al. (J. Kozloff Fish Distributors) v. United States 168 F. 2d 361 (C.C.A. 6, 1948) .....	238
Two Thousand, Six Hundred and Forty Cases of Dried Prunes; United States v. (W.D. N.C., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7277) Issued September 1945	122

## U

United States Cane Sugar Refiners' Ass'n. et al v. McNutt 138 F. 2d 116 (C.C.A. 2, 1943) .....	431
United States v. (See under name of other party)	
Urbeteit, etc. v. United States 164 F. 2d 245 (C.C.A. 5, 1947) .....	212
reversed, 335 U.S. 355 (1948) .....	249
172 F. 2d 386 (C.A. 5, 1949) .....	521
reversed, 336 U.S. 804 (1949), certiorari denied (1949) .....	560

## V

Various Quantities of * * * "Instant Alberty Food * * *" etc.; United States v. 83 F. Supp. 882 (D. of Col., 1949) .....	533
--	-----



W

	PAGE
Walsh, etc.; United States v. 331 U.S. 432 (1947) .....	337
Washington State Apple Advertising Commission et al v. Federal Security Administrator 156 F. 2d 589 (C.C.A. 9, 1946) .....	440
Washington State Grange et al. v. Federal Security Administrator 156 F. 2d 589 (C.C.A. 9, 1946) .....	440
Willapoint Oysters, Inc., v. Ewing et al (C.A. 9, 1949) .....	543
Willard Tablet Co.; United States v. 141 F. 2d 141 (C.C.A. 7, 1944) .....	80

---



# SEIZURE CASES

## UNITED STATES v. 376 DOZEN SMALL SIZE, ETC., EMERSON'S BROMO SELTZER

United States District Court for the Southern District of New York.  
May 25, 1939. Notices of Judgment Under the Federal Food,  
Drug, and Cosmetic Act, Drugs and Devices  
(No. 81) Issued May 1940.

Motion was made by the claimant to consolidate eight libel proceedings into one and have it removed to the district wherein the claimant had its principal place of business. Although the motion to consolidate will be granted, the motion for removal will not, since a claimant may not obtain a removal of a seizure case to the district of its principal place of business.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

### *[Proceedings for Consolidation]*

JOHN W. CLANCY, District Judge: This is a motion to consolidate eight libel proceedings into one and have it removed to the United States District Court for the District of Maryland, wherein the claimant, a Maryland corporation, has its principal place of business. The present proceedings are pending in the Southern District of New York, the Northern District of Georgia, the Eastern District of Tennessee, and the Middle District of North Carolina. The motion was brought under Sec. 304 (b) of the Federal Food, Drug, and Cosmetic Act, Title 21 U. S. C. A. 334, which provides in part:

"\* \* \* When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed.

The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby."

### *[Removal of Causes Contested]*

The Government has not objected to the consolidation but does object to the removal. The relevant portion of this section, in its original form in the Senate, provided:

"The United States District Court wherein the claimant's principal place of business is located, or such district court as the parties may agree upon, are hereby vested with jurisdiction to try such cases."

### *[Legislative History]*

But the House changed it to read:

"\* \* \* (1) any district, selected by the claimant, where one of such proceedings is pending; or (2) a district in a State contiguous to the State of the Claimant's principal place of business, such district to be agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, to be designated by the court to which such application was made."

This change was not accepted by the Senate. The Bill was then sent to a Committee of Conference, whence it emerged in the form in which it was finally enacted.

### *[Removal to District of Principal Place of Business Unwarranted]*

We think that the record of the Committee reports and debates in the Senate, preceding its enactment, and the Bill's language, disclose that it was the intention of the Congress that a claimant might not obtain a removal of the case for trial to the district of its principal place of business.



The Act affords the claimant the right to obtain a trial in any other district of reasonable proximity to its principal place of business unless good cause to the contrary is shown. However, claimant here has not requested any district other than that of its principal place of business and, in the

absence of such request, the Court, while granting the motion to consolidate, must deny the motion for removal, thereby effectuating a consolidation in this district which is reasonably proximate to claimant's principal place of business and wherein it saw fit to make this motion.

---

## UNITED STATES v. 32½ CASES OF MERLEK MINERAL WATER

United States District Court for the District of Arizona, December 19, 1940.  
Notices of Judgment Under the Federal Food, Drug, and Cosmetic  
Act, Drugs and Devices. (No. 513) Issued September 1942.

Seizure proceedings were instituted against mineral water on the ground that it was misbranded both as a food and as a drug. In instructing the jury, the district judge declared that under the Act the product could be considered both a food and a drug, that anything used as a compound of food is declared to be a food, and that if the water was also intended for use in the treatment and prevention of mineral deficiency diseases it would also be a drug.

Sections 201 (f), 201 (g), 304 (a), 403 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The district judge also charged the jury that the aim of the statute is to prevent deception resulting from indirection and ambiguity, as well as from statements that are false.

Sections 304 (a), 403 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

In instructing the jury, the district court also declared that if the jury found that there was a material weight of scientific opinion contrary to any of the representations made in the labeling, and no mention was made of the existence of such contrary opinion, it might find that the article was misbranded.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The district court also charged that the burden cast upon the Government was to prove its case by a preponderance of the evidence.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

### [Instructions to Jury]

THE COURT: It now becomes the court's duty, gentlemen, to instruct you as to the law that applies to this particular controversy.

### [Statute Involved]

This case was brought under the provisions of the Federal Food, Drug and Cosmetic Act, which is intended to prevent the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics. The statute pro-

vides, among other things, that "any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into, or while in interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter," and shall be liable to seizure and condemnation.

The act also provides that interested persons may claim property so seized, and "that on demand of either party, any issue of fact joined in any such case shall be tried by a jury."



*U. S. v. 32½ Cases Merlek Mineral Water**[Misbranding Alleged]*

In this case, the Government has caused 12 2-quart jugs of an article known as Merlek Mineral Water to be seized. The Government, in its libel filed in the case, has alleged the article to be misbranded in violation of the statute, and Mr. M. E. Lee, of Oakland, Calif., and Mr. Ned Johnson, of Phoenix, Ariz., who have claimed the property under seizure, have denied in their answer filed in this case that the article is misbranded in violation of the statute.

*[Question for Determination]*

There is no dispute that the goods under seizure were shipped in interstate commerce by Lee Bros. from Oakland, Calif., to Mr. Ned Johnson, Phoenix, Ariz., on or about May 18th, 1940, or that they were in the possession of Mr. Ned Johnson, of Phoenix, Ariz., when they were seized. I, therefore, charge you that the sole question for you to determine, from the evidence in the case, is whether or not the article under seizure is misbranded in violation of the statute, as alleged by the government.

If you find from the evidence that the article is misbranded, then your verdict should be for the Government. If you find from the evidence that the article is not misbranded, then your verdict should be for the claimants.

*[Nature of Action]*

This action is one of *rem*: that is, the Government's complaint is against the Merlek Mineral Water that has been seized, and not against the gentlemen that have appeared to claim it. The intent of the claimants has no bearing on this case. Your part in this proceeding is to determine a question of fact. This question of fact is very simple. Is this water misbranded because of false or misleading statements made about it in the label and circular that has been received in evidence? You are entitled to read and consider the statements made about this water in the label and in the circular, and decide whether or not they are false and misleading in any particular.

You gentlemen would have no objection to the jury taking the exhibits into the jury room?

Mr. PERRY: No, your honor.

Mr. WOOD: No, your honor.

*[Factors for Consideration]*

THE COURT: Very well. In reaching your decision, you should take into consid-

eration the nature of this water and what it is composed of. Under the law, this water can be considered both a food and a drug. The reason for this is that the directions for its use recommend that some of it be placed in drinking water or in milk. Drinking water and milk are both foods under this law, and anything used as a compound of a food is also declared to be a food. If you should find that the water is also intended for use in the treatment and prevention of mineral deficiency diseases of the human body, it would then also be a drug under the law. So, no matter whether you believe that Merlek Mineral Water is a food or a drug, or both a food and drug, your duty is the same, that is, to decide whether or not it is misbranded, as alleged in the libel.

In reaching a determination as to whether or not the water is misbranded, you should base your decision entirely on the evidence you have seen and heard at this trial, and should be guided by no other considerations.

If you decide that this water will do all the things that are claimed for it in the label and circular, and that the labeling is not false and misleading in any respect, you should render a verdict for the claimants; but if you should find from the evidence that while the water may be of help in doing some of the things claimed for it in the label and circular, if you find that it will not do all of the things claimed for it, and that in such respect the labeling is false or misleading, it is your duty to find the water to be misbranded, and your verdict should be for the Government. That is the libelant.

*[Ambiguous Statement]*

The statute under which this case has been tried condemns every statement in the labeling of the article Merlek Mineral Water which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of this statute is to prevent that resulting from indirection and ambiguity, as well as from statements that are false. It is not difficult to choose statements that will not deceive.

If you find from the evidence that there are any false and misleading statements in the labeling involved in this case, your verdict should be for the Government, as I have stated before.



*[Failure To Reveal Material Facts]*

In determining whether or not any statements made in the labeling of the article Merlek Mineral Water are misleading, you should take into account, among other things, not only representations made or suggested by such statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations.

If you find from the evidence that there is a material weight of medical and scientific opinion contrary to any of the representations made in the labeling of Merlek Mineral Water, and no mention is made of the existence of such contrary opinion in said labeling, you may find that said article is misbranded.

*[Preponderance of Evidence]*

The law casts upon the Government the burden of proving this case by what is known as the preponderance of evidence. Preponderance of evidence simply means the greater weight of the evidence. It is not dependent upon the number of witnesses who have testified in the case, but it is rather the quality of the evidence instead of the—or the quality rather than the quantity. If the evidence should be in your minds equally divided, then the Government, of course, hasn't sustained this burden of proof, and your verdict should be for the claimants.

*[Credibility of Witnesses]*

You are the sole judges of the credibility of the witnesses; that is to say, the extent to which you will believe the witnesses who have testified before you. It is your duty to reconcile the conflicting testimony of various witnesses and conflicting statements, so far as it may reasonably be done.

*[Expert Testimony]*

Witnesses, those who are supposed to know more than the ordinary person about such subjects, such as chemists and physicians, have been permitted to give their opinions as to various matters. Opinion evidence is not binding upon you, but should be considered in connection with all other evidence in the case. Should you believe it, you may accept and follow it. By an opinion, I mean a statement or a conclusion arrived at by the witness from experience or from knowledge, as distinguished from testimony concerning the direct fact.

That is, I might say that this building was constructed of brick. That would be a statement of fact. If I say it was worth twenty thousand or a hundred thousand dollars, that would merely be my opinion.

You are the sole judges of the value of opinion evidence. Of course, an opinion is worthless unless it is the honest opinion of the man who states it. If you deem it is his honest opinion, then its value depends upon how much he knows about the subject concerning which he is testifying. If he is fairly experienced, fairly grounded in his subject, if his opinion is the result of mature reflection, if he is a man of strong logical intellect, his opinion would be entitled to great value. If, on the other hand, he was incapable of logical thinking, or if he was not well grounded in his subject, nor familiar with the facts upon which his conclusion is assumed to be based, then, of course, his opinion would be of little or no value; and it is for you to decide what value you will give to the opinion evidence that you have heard.

*[Opinion Evidence]*

Now, a great deal of the evidence of the witnesses who have testified concerning their own ailments is in the nature of opinion evidence. Those witnesses who testified that they had well known, easily discernible diseases, or easily told diseases, I will say, such as headaches and constipation, or something of that sort, of course, there will be very little reason to doubt that they knew what they had. But if one testified that he thought that he had some more obscure disease, more difficult to diagnose, and his diagnosis of what he had depended entirely upon his own opinion, and he was unable to make such a diagnosis, his opinion would be of very little value. Those are matters for you to take into consideration in weighing the testimony of the witnesses.

*[Interest of Witnesses]*

You may also consider the interest of the witnesses, if they have any, in the outcome of the case, their affiliation with either of the parties, their manner of testifying, their appearance upon the witness stand, whether their testimony was logical or otherwise, these and any or all other subjects touching the credibility of the various witnesses, you may take into consideration; and having considered all matters, you will give the testimony of each and every witness such



*U. S. v. 6 Devices, "Electreat Mechanical Heart"*

weight as you find it is entitled to receive. That is entirely within your province, and if upon a consideration of all the evidence you find that the statements charged in the libel are false in any substantial part, you will find the product to be misbranded. Upon the other hand, if you do not find that the statements charged in the libel are false, then, of course, your verdict should be for the claimants, and you will find that the article has not been misbranded.

Any suggestions, gentlemen, or any objections?

Mr. PERRY: No, your honor.

Mr. WOOD: No, we have none.

*[Forms of Verdict]*

THE COURT: Forms of verdict have been prepared for your guidance. One form reads: "We, the jury, duly empaneled and sworn in the above entitled action, upon our

oaths do find for the libelant." The libelant, you understand, is the Government.

The other one: "We, the jury, duly empaneled and sworn in the above entitled action, upon our oaths do find for the claimants, Mr. Johnson and Mr. Lee."

*[Deliberations of Jury]*

After you retire to your jury room, you will select one of your number to act as your foreman, and proceed with your deliberations. After you have agreed upon a verdict, you will have it signed by your foreman and returned to open court. Any verdict agreed upon must, as you know, be unanimous. Swear the bailiffs.

[The jury, after deliberation, returned a verdict for the Government and on January 6, 1941, judgment was entered condemning the product and ordering that it be destroyed.]

## UNITED STATES v. 6 DEVICES, "ELECTREAT MECHANICAL HEART"

United States District Court for the Western District of Missouri, Western Division. February 28, 1941. 38 F. Supp. 236.

In a seizure action to condemn devices on a misbranding charge based on misleading labeling, claims made for the devices in accompanying literature were held to be misleading.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

It was beyond the issues to consider whether, if the devices were properly labeled, they could be barred from the mails and interstate commerce.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The question of whether the manufacturer acted in good faith was not an issue in the proceeding.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Charles F. Lamkin, Jr., Assistant U. S. Attorney, Kansas City, Mo., for plaintiff.

Frederick E. Whitten, Kansas City, Mo., for defendant.

### Memorandum Opinion

COLLET, District Judge: On March 6, 1940, six devices called Electreat Mechanical Hearts were mailed in interstate commerce<sup>1</sup> from Peoria, Illinois, to Kansas City, Missouri, for the purpose of sale at the latter place. The devices were seized by the Government and libel proceedings instituted at

Kansas City, Missouri, for the purpose of bringing about the destruction of the devices.

*[Intent of Act]*

The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (Title 21, Sec. 301 *et seq.* U. S. C. A.) authorizes the destruction of misbranded devices.<sup>2</sup> The term "de-

<sup>1</sup> Sec. 321 (b): "The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof \* \* \*"

<sup>2</sup> Sec. 334 (a): "Any \* \* \* device \* \* \* that is \* \* \* misbranded when introduced

into or while in interstate commerce \* \* \* shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found \* \* \*"



Federal Food, Drug, and Cosmetic Act  
*U. S. v. 6 Devices, "Electrical Mechanical Heart"*

"vice" is defined in the Act.<sup>3</sup> The Statute provides that if the device is alleged to be misbranded because of misleading labeling, in the determination of that question there shall be taken into account, among other things, not only representations made in the labeling but also the extent to which the labeling fails to reveal material facts.<sup>4</sup> "Labeling" is defined to include all labels and other written, printed, or graphic matter upon the article or any of its containers or wrappers or accompanying the article.<sup>5</sup> The libel charges false and misleading labeling. The good faith of the manufacturer is not an issue. The inherent dangerousness of the device or lack of it is of no consequence. The issue is simply whether the claims made for the device are false or misleading.

[Representations]

The principal and most numerous claims made for the device are contained in a booklet which accompanied the devices seized. There the device is referred to as "The Mechanical Heart." In the language of the booklet it will relieve pain, strengthen weak eyes, soothe sore eyes, improve the hearing, cure earache, moisten dry noses or dry running noses, thicken thin lips, relieve toothache, strengthen the voice, relieve sore throat, build up weak lungs, relieve pleurisy, strengthen the kidneys, cure lumbago, relieve constipation, soothe the piles, is good for neuritis, subtracts pain from burns, relaxes the muscles in a stiff thumb and soothes the pain in a mashed finger, retards or accelerates the development of a boil, heals broken noses, relaxes muscle cramps, is good for varicose veins and will warm cold feet or stop the foot from perspiring.

[Scope of Booklet]

The booklet undertakes to demonstrate "why the good die young," what the "fa-

ther and mother" of disease is, the cause of wakefulness, how to grow strong, and the corrective qualities of the device in each instance.

It then gives specific directions about how to use the Electreat for the treatment of headache, neuralgia, sinus congestion, neuritis, sore throat, weak lungs, athletic strains, lumbago, rheumatism, gout and tired feet, stomach, indigestion and cramps, kidney and bladder trouble, liver disorders, constipation, piles, sexual weakness male and female, menstruation, menopause, enlarged prostate, paralysis, deafness and catarrh, toothache, eye ailments, asthma, hay fever, flu, broken bones, burns, cuts, sores, hardening of arteries, cramps of the calf, nervousness, to reduce weight or increase weight as desired, beautification of the skin, enlarge the bust and increase the flow of milk, and to stop falling hair. Then follows a number of testimonials affirming the efficacy of Electreat for the treatment of many and sundry bodily ailments ranging from congenital and jake-leg paralysis through heart ailments, piles, rejuvenation, to appendicitis and female trouble. The testimony of the manufacturer who intervened in the cause as claimant, indicates that the theory upon which the multitudinous claims were made was that the instrument produces a faradic electrical current with the alternating impulses occurring at the rate of from 140 to 180 times a second, which would cause the muscles and muscular tissue of the human body to contract and relax with beneficial results. The instrument is simple enough. It consists of a cylindrical metal container having much the appearance of an ordinary flashlight, approximately ten—eleven inches long, an inch and a half in diameter with two small flashlight batteries in one end and in the other two coils. The primary coil is wound upon a soft iron core. The secondary coil is so wound that it may be moved longitudinally over the primary coil by means

<sup>3</sup> Sec. 321 (h): "The term 'device' \* \* \* means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

<sup>4</sup> Sec. 321 (n): "If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design,

device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

<sup>5</sup> Sec. 321 (m): "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."



of a button attached to it and extending through the metal cylinder much as the switch on an ordinary flashlight is arranged. A common vibrator such as might be used on the old-fashioned doorbell, makes and breaks the current from the battery and transforms the galvanic current from the battery into the faradic or alternating current, which is delivered to the body through a projection on one end of the instrument. The strength of the charge delivered to the body from the instrument is increased or decreased by means of sliding the secondary coil further over or away from the primary coil.

[*Government Testimony*]

An adequate amount of highly respectable and convincing testimony was offered by the Government to demonstrate that even the principle sought to be followed by the makers of the instrument could not be applied with this instrument. It was explained that the speed or rapidity at which muscular tissue could contract and relax was much less than the rate at which the vibrations occurred in this instrument and the alternating impulses were given, and hence the only effect from the use of the instrument on the muscles of the body was to cause them to contract and remain so until the instrument was removed, the batteries wore out, or the muscles relaxed from fatigue. Many of the particular claims made for the instrument were specifically referred to by the witness. In each instance the explanation of why the instrument could not produce the results claimed for it was most convincing.

[*Expert Testimony*]

Among others appearing for the Government was the eminent Physiologist, Dr. Carlson. His testimony and the illustrations he gave supporting his conclusions were in all respects as fully convincing of the accuracy of his judgment as was his test for the determination of which of two fluids was a sugar solution<sup>6</sup>.

The extent of the accuracy of the actual claims made for the Electreat in the literature accompanying it may be summarized much as one of the witnesses expressed it, when, in describing a diagram of the human anatomy with accompanying descriptive matter which appeared in one of the Ex-

hibits, he stated that there was an element of truth in the diagram, the element of truth being—that the head was on the right end in the picture and the "rump" appeared in the proper position. From a practical standpoint, the benefit to be derived from the use of the instrument was tersely stated by one of the several leading physicians of Kansas City, to be that the use of the instrument would not injure one if there was nothing the matter with him, but that if a person was suffering from any disorder or ailment its use might and probably would be injurious.

[*Falsity of Claims*]

Further detailed reference to the facts should be unnecessary to demonstrate the irresistible conclusion arising from the evidence that the claims made for the devices in the literature accompanying them were as falsely misleading as might well be possible by the use of the English language. The conclusion follows that the Act of Congress has been violated and the requested order for the destruction of the devices must be made.

[*Effect of Proper Description Not in Issue*]

It is beyond the issues in this proceeding to consider the question of whether, if the devices were properly described and labelled and their efficacy stated without exaggeration, the devices could be barred from the mails and interstate commerce. Hence, evidence bearing upon that question, admitted subject to objection, is excluded from consideration.

[*Good Faith Not in Issue*]

Neither is the question of whether the manufacturer acted in good faith in an honest belief that the devices would do the things claimed for them an issue in this proceeding. The Government does not seek a penalty in this case other than the destruction of the devices. Evidence bearing upon that question, likewise admitted subject to objection, should also be excluded.

[*Findings and Conclusions*]

Formal findings of fact and conclusions of law are filed herewith. Judgment will be entered in accordance with the views herein expressed.

<sup>6</sup> *Time* magazine, February 10, 1941, page 44. L.C. 47: "Another time he had two beakers of liquid before him: one containing urine, the

other, sugar solution. He stuck his finger in one of the containers, tasted it and said: 'Ya, dot's sugar.' "



UNITED STATES v. 11¼ DOZEN PACKAGES OF ARTICLE  
 LABELED IN PART "MRS. MOFFAT'S SHOO FLY  
 POWDERS FOR DRUNKENNESS"

United States District Court for the Western District of New York.  
 June 17, 1941. No. 567. 40 F. Supp. 208.

A seizure proceeding is *in rem*. The burden rests upon the Government to establish its case only by a fair preponderance of the evidence.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

In a seizure action instituted against a drug on the ground that false claims had been made in the labeling, it was not necessary for the Government to show intent to deceive and defraud.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Stating that the article was "for drunkenness" was the equivalent of saying that it was a "cure, mitigation, treatment, or prevention" of drunkenness; the necessary implication was that it was for relief from drunkenness to at least some extent.

Sections 201 (n), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

A drunkenness remedy containing antimony and potassium tartrate (tartar emetic) was held to be dangerous when used in the dosage prescribed on the label.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

Evidence that powders in question had been sold for 60 years, and that over 50,000 of the powder packages had been sold yearly for ten years, was held competent.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Testimony that no complaints had been received by the manufacturers was held to be hearsay and incompetent.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The weight to be given expert testimony is for the court to determine.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The testimony of physicians, based largely on their studies but not upon the actual use of the article in question, is not to be disregarded.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

George L. Grobe, U. S. Attorney, and Joseph J. Doran, Asst. U. S. Attorney, both of Buffalo, N. Y., for libelant.

Merwin, Paul, Lesswing & Hickman, Wortley B. Paul and Louis Burman, of counsel, Buffalo, N. Y., for claimant.

*[Nature of Proceedings]*

KNIGHT, District Judge: The libelant seeks condemnation of certain articles of alleged drug products described as "11¼ Dozen Packages of an article labeled in part: 'Mrs. Moffat's Shoo Fly Powders for Drunkenness.'" Libel is brought under the provisions of the Federal Food, Drug and Cosmetic Act of June 25, 1938, Title 21 U. S. C., and is based upon the claim that the aforesaid articles are misbranded under

subdivision (a) and (j) of Section 352 of Title 21 U. S. C.

It is admitted that the articles in question were shipped in interstate commerce, that is, from the State of Pennsylvania to the Ellicott Drug Co., at Buffalo, New York, on November 2, 1940, by the intervenor, M. F. Groves' Son & Co., who concededly is the owner and manufacturer of the articles in question, and that a representative of the libelant during said month purchas-



*U. S. v. 11¼ Dozen Packages "Mrs. Moffat's Shoo Fly  
Powders for Drunkenness"*

ed a quantity of the articles in question from the last-named company. The articles contained on the average 3.2 grains of potassium antimony tartrate (tartar emetic) and no other constituents.

[*Drug Defined*]

Section 321 (g) Title 21 U. S. C. provides, among other things, that a drug means "(2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals," and "(3) articles (other than food) intended to affect the structure or any function of the body of man \* \* \*," and (k) (same section) defines a label as "a display of written, printed or graphic matter upon the immediate container of any article." The label on the articles in question clearly purports the content to be for use in the "diagnosis, cure, mitigation, treatment or prevention" of drunkenness.

[*Label in Question*]

The label in question is as follows:  
(Trade Mark)

MRS. MOFFAT'S  
SHOO FLY POWDERS  
FOR DRUNKENNESS

6 Powders—18 GM. Each

Antimony & Potassium Tartrate  
In Use 60 Years Use according to  
directions

M. F. GROVES' SON & CO.  
Since 1832

803 South Front Street Philad'a, Pa.

Sold to Druggists only  
Price, 50 Cents a Box

19574 E Nov 14 1940

DIRECTIONS—One of the Powders may be given in Beer, Coffee, Tea or any other liquid.

*Never give more than one Powder a day*

These powders are intended to be used by adults only, and should be kept from children.

[*"Misbranded" Defined*]

Section 352, Title 21, *supra*, provides: "A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular" and "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." Such misbranded article is liable to condemnation "when introduced into or while in interstate com-

merce \* \* \*, or at any time thereafter, \* \* \*" Section 334, Title 21, *supra*.

[*Issues*]

The questions at issue are (1) whether the labeling of the article aforesaid is false and misleading, and (2) whether the drug is dangerous to health when used in the dosage prescribed on the label. The libel must be sustained on the determination of either question in the affirmative.

On behalf of the government five physicians testified with respect to the effect of the use of antimony and potassium tartrate (tartar emetic) "for drunkenness," and with respect to the danger to health in its use in the dosage prescribed. On behalf of the claimant an officer of the intervenor gave testimony as to the amount of the article in question sold over a period of years.

[*Burden of Proof*]

The proceeding is *in rem*. The burden rests upon the government to establish its case only by a fair preponderance of the evidence. *United States v. 5 One-Pint Bottles, etc.*, 9 F. Supp. 990; *United States v. 23½ Doz. Bottles, etc.*, 44 F. (2d) 831.

[*Proof of Intent To Deceive Not Necessary under Present Act*]

A contention made by the intervenor is that it is necessary for the government to show intent to deceive and defraud. While this was held to be the law under the Act of June 30, 1906, sec. 8 as amended by the Act of August 23, 1932, such is not the law under the Act of June 25, 1938, *supra*. The former statutes provided that an article should "be deemed to be misbranded in case of drugs; \* \* \* if its package or label shall bear \* \* \* any statement \* \* \* regarding the curative \* \* \* effect \* \* \*, which is false and fraudulent." *Chichester Chemical Co. v. United States*, 49 F. (2d) 516, held that the government must prove actual intent to deceive. Under the present statute a drug is deemed to be misbranded "if its labeling is false or misleading in any particular." Intent is not necessary to be proved. Further, the aforesaid Act of 1906, section 8, required that the misbranding must be "false and misleading." These are the words of the present statute. Under the Act of 1906 numerous cases held that it was not necessary to show intent. In this Circuit we find *United States v. Scaduto*, S. D. N. Y. decided January 16, 1920; *Von Bremen et al. v. United States*, 192 F. 904.



Federal Food, Drug, and Cosmetic Act  
*U. S. v. 11¼ Dozen Packages "Mrs. Moffat's Shoo Fly  
 Powders for Drunkenness"*

[*Non-Applicability of Authority Cited*]

It is urged that merely stating that the article is "for drunkenness" is not sufficient to constitute offence of misbranding. The use of the words "for drunkenness" is the equivalent of saying that it is a "cure, mitigation, treatment or prevention" of drunkenness. The necessary implication is that it is for relief from drunkenness to at least some extent. In *United States v. Natura Co.*, 250 F. 925, cited by the intervenor, the indictment charged misbranding where the label stated that the drug was "a natural remedy for certain specified diseases, and that it had proved effective in the treatment of such diseases." There it was claimed that the word "remedy" was synonymous with "cure." This was a criminal case, and it was held that the plaintiff had not established beyond a reasonable doubt that the statements on the label were both "false and fraudulent." This has no controlling bearing here.

[*Government's Evidence*]

The physicians testifying on behalf of the government were, one a pharmacologist, one an internist, one a neuropsychiatrist, one a specialist in therapeutics. Each testified that antimony and potassium tartrate (tartar emetic) is not a curative for drunkenness, that it is a drug not properly useable in the treatment of drunkenness, and that its use in the dosage shown on the label herein is dangerous to health. Each of these physicians had had extensive practice in his specialty. Each testified that the medical profession had long recognized that tartar emetic was a drug dangerous to be administered through the mouth; that its use through the mouth has been abandoned in the teaching field; and that the standard textbooks treat it as a poison. The testimony of these physicians is to the effect that tartar emetic taken through the mouth irritates the lining of the stomach and intestines, produces various injurious effects on various other organs of the body; that it is cumulative in its effect; that when taken in increased doses it causes nausea, vomiting, diarrhea and retching; and after absorption affects the liver and kidneys and increases the heart rate; that through the loss of the control of the muscles of the stomach the vomitus may be swallowed causing pneumonia. They say the medical

profession for many years has not prescribed it to be taken through the mouth, except as it is so used in so-called Brown's Mixture, which contains 1/70 of a grain of this drug, and that its present use is almost entirely intravenous or intramuscular as a treatment for numerous tropical diseases. Brown's Mixture is used as a carrier with other drugs to make a cough syrup. They have given many other details pointing out the other effects from the use of this drug in the dosage prescribed.

[*Pharmaceutical Authorities*]

The Pharmacopeia (Ed. 1936) states the average dosage when taken internally as 1/20 of a grain. The National Standard Dispensary (Ed. 1907) gives it as one-half to one grain taken every fifteen minutes until several doses are taken or till emesis occurs. I find on reference to the edition of 1938 no reference is made to any repetition of the dose and that the dosage "usually is about ½ grain (.03 gm.)." The National Standard Dispensary (Ed. 1907) also states that tartar emetic at one time was largely employed as an "expectorant, diaphoretic, emetic, sedative, antiphlogistic, and counter-irritant, but at present its use has become greatly limited." It states it is an irritant and that continued application causes "a pustular eruption followed by deep sloughing;" that "antimony depresses the sensory side of the spinal cord; \* \* \* lowers \* \* \* the pulse-force;" and blood pressure; that it is an irritant to the stomach and intestines and in toxic dose produces violent gastro-enteritis; that the purging following overdose of the drug "is an effort made by the intestines to eliminate the poison, and is due also to the intense intestinal inflammation;" that it is very slowly absorbed and slowly eliminated; that as an emetic this drug causes great prostration and muscular relaxation, it is badly borne by children, by the aged, and by those who are enfeebled by disease; and never should be used when "gastro-intestinal irritation or inflammation is present;" and that chronic poison sometimes results from the frequent administration of this drug.

The Edition of 1937 of the National Standard Dispensary further states this:

"Its emetic action is very certain, powerful, prolonged, but accompanied by much depression. \* \* \* although because of the promptness of its emetic action recovery may occur after very large amounts one



*U. S. v. 11¼ Dozen Packages "Mrs. Moffat's Shoo Fly  
Powders for Drunkenness"*

case is on record in which two grains proved fatal."

This work gives the dosage when used intravenously or intramuscularly at one-half to two grains given every alternate day and as a dosage internally "as a diaphoretic or expectorant it may be given in quantities of from 1/40 to 1/8 grain. If used as an emetic the dose usually is about 1/2 grain."

The conclusion here is inescapable both that the label in question is false and misleading and that the drug is dangerous to health when used in the dosage prescribed on the label. While it may seem that the use of this emetic in some amount may be beneficial in cases of drunkenness because of the fact that it clears the stomach, the fact is that alcohol is absorbed into the blood stream within twenty minutes to half an hour after being taken into the stomach and, therefore, the emetic could not usually affect the action of the alcohol.

[*Manufacturer's Evidence*]

The only evidence offered by the intervenor was that given by an official of the claimant to the effect that the powders in question have been sold for upwards of 60 years; that over 50,000 of the powder packages have been sold yearly for the last ten years and that not a single case of harm or injury has ever been reported by any one to the manufacturers. Objection was raised to the reception of all this testimony. It was received subject to be stricken, if the court later so decided. It is believed that the testimony as to the number of packages of the powder that had been sold and the period of years over which it had been sold is competent and the ruling as made stands. However, the testimony that no complaints had been received is incompetent. *Goldstein v. United States*, 63 F. (2d) 609. It is clearly hearsay.

[*Preponderance of Testimony*]

The intervenor urges that the testimony on behalf of the intervenor is not outweighed by the testimony given by the experts called by the government. We are to bear in mind in this connection that the only testimony now in the record offered by the intervenor is with reference to the number of packages sold and the period of time over which they were sold. While the intervenor cites numerous cases in which con-

sideration had been given to the weight of expert testimony, none of these hold that it is to be given no weight. The weight of such testimony is for the court to determine. These cases present somewhat comparable situations where physicians have testified as experts: *United States v. Lee*, 107 F. (2d) 522, cert. denied 309 U. S. 654; *United States v. Dr. David Roberts Vet. Co.*, 104 F. (2d) 785; *United States v. American Laboratories*, 222 F. 104; *United States v. W. B. Wood Mfg. Co.*, D. C. E. D. Mo., decided May 12, 1921; *Eleven Gross Packages etc. v. United States*, 233 F. 71; *Chichester Chemical Co. v. United States*, *supra*; *Hall v. United States*, 267 F. 795. The testimony of these physicians is largely based on their studies as physicians but not upon the actual use of the article in question. Certain of these physicians have testified to personal observation of the use of the drug in question. Testimony of these men is not to be entirely disregarded because they testified as experts. As against the testimony that large numbers of packages of this drug have been sold during many years, we have the testimony of all of the five physicians that the drug itself is not a cure for drunkenness and that its use in the dosage prescribed is dangerous to health. Each of these physicians went into great detail in explaining the nature of the drug and its reactions upon the human system when taken internally.

[*Conclusion*]

It is not necessary to decide whether the drug when taken in the dosage of any specific number of grains less than 3.2 may properly be taken in the treatment of drunkenness or whether such dosage would be dangerous to health. I do decide that the articles in question are misbranded, since the labels thereon are false and misleading, because antimony and potassium tartrate in the dosage of 3.2 grains (the average in the articles analyzed) is not a "cure, mitigation or treatment" for drunkenness as purported to be and also that it is misbranded, because the use of the drug in the dosage of 3.2 grains is dangerous to health.

[*Ruling*]

Libelant is entitled to an order adjudging and decreeing that the articles of drug product aforesaid be condemned according to the provisions of the statute.



## UNITED STATES v. 15 CARTONS OF SEKOV REDUCER

United States District Court for the Southern District of Texas. September 18, 1941. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1002) Issued March 1945.

Seizure proceedings were instituted against a drug on the ground that it was misbranded when introduced into interstate commerce. On motion to remove the case to another district, it was held that the number of seizure actions which could be brought was not limited under Section 304 (a) (2), and that the case, therefore, might not be removed.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

A claimant is not necessarily entitled to have a seizure case transferred to the district in which it has its place of business, but only to a district of "reasonable proximity" thereto.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Good cause had been shown for not transferring the case, since it appeared that the product was in the hands of a person other than the claimant when seized and that many of the witnesses were in the district where the case was instituted.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

### [*Suit To Condemn Sekov Reducer*]

KENNERLY, District Judge: This is a suit by the United States of America to condemn under the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (Title 21, Sections 301 to 392, U. S. C. A.), Fifteen Cartons, more or less, of articles called "Sekov Reducer." Such articles were at the time of the filing of said suit, and are now, situated in the City of Houston in this Division and District. They have been seized by the Marshal. His Return shows that they were in possession of Sekov Reducing Studio when seized.

### [*Motion To Transfer Suit*]

Sekov Corporation, a claimant of such articles (for convenience called Claimant), has filed a Motion to transfer the suit to the District Court of the United States in the District in which Claimant says it has its principal place of business, i. e., Hollywood, in the Southern District of California. This is a hearing on such Motion under Local District Court Rule 25. The matter is to be determined from the pleadings of the parties which for the purpose of this hearing will be regarded as stating the facts.

### [*Statutory Provisions Involved*]

1:—The particular provision of such Act upon which Claimant relies to support such Motion is the following portion of Section 334, Title 21, U. S. C. A.:—

"In any case where the number of libel for condemnation proceedings is *limited* as above provided; the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

The Government answers the Motion with the claim that in this case the number of libel for condemnation proceedings is *not limited* under that portion of Section 334 which reads as follows:—

"(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 344 or 355, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, that no libel for condemnation



shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply:— \* \* \*

“(2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.”

[Case Not of Type To Be Transferred]

I think the Government is right, and that this is not a case that may be transferred.

[Good Cause Shown for Not Transferring Case]

2:—It will be observed also from Section 334 that a claimant such as is the Claimant here is not necessarily entitled to have the case transferred to the District in which it has its place of business, but only a District of “reasonably proximity” thereto. But that such transfer shall take place unless good cause to the contrary is shown.

Not only is this a case where proceedings are not limited, but good cause is shown why it should not be transferred. It not only appears that the articles are situated in this District, but were in the hands of a person other than claimant when seized and that many of the witnesses are in this District.

[Motion for Transfer Denied]

Claimant’s motion will be denied. Let an Order be prepared and presented accordingly.

## UNITED STATES v. 1,375 CASES OF TOMATO PASTE

United States District Court for the District of Connecticut. January 14, 1942.

Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 3761) Issued May 1943.

Seizure proceedings were instituted against tomato paste on the ground that it consisted in whole or in part of a decomposed substance. The first clause of Section 402 (a) (3) plainly banned all products composed in whole or in part of any decomposed substance, and the second clause went on to add to the ban substances which were unfit for food for any other reason.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Proof that the product proceeded against is actually unfit for food is no part of the Government’s case in an action under Section 402 (a) (3).

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Under the Food and Drugs Act of 1906, the courts had consistently decreed the condemnation of decomposed substances without proof of any injurious effect upon health, and the 1938 Act followed the earlier statute on that point so closely that it was only reasonable to infer that Congress intended to continue the substance of the earlier statute as judicially construed.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

[Issue of Law]

HINCKS, Circuit Judge: The Federal Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040, 21 U. S. C. A. 342) classified food as “adulterated,” and hence subject to condemnation if shipped in interstate commerce under 21 U. S. C. A. 334, “if it consists in whole or in part of any filthy, putrid,

or decomposed substance, or if it is otherwise unfit for food.” The only issue of law raised in this case is whether under this provision of the act the Government is entitled to a decree upon proof of a substantial amount of decomposed matter in the shipment, or whether it must also prove that the product was unfit for food.



*[Contention of Claimant]*

The claimant contends that the clause "or if it is otherwise unfit for food" modifies the preceding class of substances; that the use of the phrase "*otherwise* unfit for food" necessarily imports that the class of decomposed substances which is subject to condemnation must also, within the legislative intent, be unfit for food.

*[Relation of Clauses in Question]*

With this I cannot agree. The whole subject matter of this subdivision of the statute is covered by two coordinate "if" clauses, and the second "if" indicates plainly that the second clause introduced thereby is coordinate and independent rather than a qualification of the antecedent clause. The first clause plainly banned all products composed in whole or in part of any decomposed substance, and the second clause went on to add to the ban substances which were unfit for food for any other reason.

*[Construction Questioned]*

To be sure, the other subdivisions of section 342 (a) specify as characteristics of the banned products that they shall be "deleterious," "injurious to health," or "the product of diseased animals," etc. These specified characteristics thus became essential prerequisites to be proved in cases brought under these subdivisions of the act. But in the first clause of subdivision (3) of section 342 (a) the sweeping ban of products consisting in whole or in part of any decomposed substance imports a Congressional finding that the presence of any substantial amount of rot in any food product is at least a sign of danger which alone justifies the exclusion of the product from unrestricted circulation in interstate commerce. That being so, proof that the product is actually unfit for food is no part of the Government's case in a prosecution under section 342 (a) (3). And there is no question here that the classification of the act has a reasonable relation to its objective, or that the objective was a proper one. For the claimant does not attack the validity of the statute; it raises only the question of its proper construction.

*[Legislative History]*

If there can be any doubt as to the propriety of my conclusion, the doubt is set at rest by the history of this legislation. The Food and Drugs Act of 1906 (34 Stat. 769, 21 U. S. C. A. Sec. 8) by subdivision 6 of

section 8 subjected to condemnation products consisting "in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter."

*[Construction of 1906 Act]*

Under this act the courts have consistently decreed the condemnation of decomposed substances without proof of any injurious effect upon health. *U. S. v. 133 Cases of Tomato Paste*, 22 Fed. Supp. 515; *Knapp v. Callaway*, 52 Fed. (2nd) 476; *U. S. v. Krumm*, 269 Fed. 848; *A. O. Andersen & Co. v. U. S.*, 284 Fed. 542; *U. S. v. 200 Cases of Canned Salmon*, 289 Fed. 157; *U. S. v. 200 Cases of Catsup*, 211 Fed. 780. These cases are not at all inconsistent with the observation frequently made (e. g., *U. S. v. Lexington Mill & Elevator Co.*, 232 U. S. 399) that the primary objective of the statute was to prevent injury to the public health. Rather, they recognize, at least tacitly, the power of Congress to decide for itself what classes of products in interstate commerce might endanger the public health. It is true that in some of these cases the judge in his opinion stated that the particular subject matter of condemnation with which the court was there concerned was unfit for food. But in none of the cases cited, nor in any other case that I have found, has it ever been held that a finding by the court that the subject matter was unfit for food was essential to a decree: a bare finding that the subject matter consisted at least in part of decomposed matter was legally sufficient.

*[Intent of Congress]*

Such then was the uniform construction of the earlier act of 1906. And the act of 1938 follows the earlier act (on this point) so closely that it is only reasonable to infer that Congress intended to continue the substance of the earlier act as judicially construed. This conclusion is further confirmed by Senate Report No. 361, March 13, 1935, on S. 5, calendar 375, 74th Congress, First Session, introduced by Senator Copeland on January 3, 1935. This report states:

"The provisions of section 301 (2), (3), and (5) (later incorporated into 21 U. S. C. A. 342 (a)) dealing with filthy food and food from diseased animals are essentially the same as those of the present law."



And the report of the Committee on Interstate and Foreign Commerce, 75th Congress, Third Session, on S. 5, states:

"The measure \* \* \* amplified and strengthens the provisions to safeguard the public health."

Thus clearly Congress intended that the clause "or if it is otherwise unfit for food," which the act of 1938 added to the earlier act, should enlarge rather than restrict the class of products subject to condemnation.

Some of the Government witnesses in their testimony took the position that the product here involved, although not deleterious to health, was nonetheless unfit for food. As my findings in paragraph 7 show, I have been unable to find any convincing proofs here to substantiate this distinction.

*[Prosecution of Minor Violations]*

But the mere fact that under my construction of the act cases may occasionally occur—of which this is perhaps one—in which a product is condemned though not actually unfit for food, by no means demonstrates that I have erroneously construed the act. It suggests only that Congress considered that the unrestricted circulation in interstate commerce of foods containing

decomposed substances was a practice fraught with such dangerous tendencies that that broad class of substances should be prescribed. But section 306 of the act, 21 U. S. C. A. 336, vests a broad discretion in the Secretary of Agriculture to forego the prosecution of "minor violations." Thus Congress definitely recognized that cases might occasionally fall within the ban of the act as having a dangerous tendency, even though the tendency, in the judgment of the Secretary, was too slight or remote to justify prosecution. In other words, the *degree* of the violation is important only for its effect upon the administrative discretion; it affects not at all the scope of the legislative ban which the judicial power when once invoked must apply.

*[Judgment of Condemnation]*

[On April 18, 1942, judgment of condemnation was entered, and the product was ordered released to the claimant under bond, conditioned that certain codes which previous examination had shown to contain decomposed material be separated from the lot and destroyed, and that the balance be examined further and the bad portion separated and destroyed under the supervision of the Food and Drug Administration.]

## UNITED STATES v. RESEARCH LABORATORIES, INC.

United States Circuit Court of Appeals for the Ninth Circuit. No. 9898.  
February 24, 1942. 126 F. 2d 42.  
Certiorari denied, 317 U. S. 656 (1942).

The libel did not state directly and positively, as a competently drawn libel would have stated, that the product proceeded against was misbranded when introduced into or while in interstate commerce.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Statements in the libel must be taken as true on exception that the libel fails to state a cause of action.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

Since packages and circulars containing claims alleged to be false and misleading had a common origin and a common destination and arrived at their destination simultaneously, they accompanied each other, regardless of whether, physically, they were together during their journey.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

Congress did not exclude from the definition of "labeling" printed matter which constitutes advertising.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

The rule of strict construction has little or no application to statutes designed, as is the Federal Food, Drug, and Cosmetic Act, to prevent injury to the public health.

Title, Federal Food, Drug, and Cosmetic Act.



The power of a district court to condemn misbranded articles is not in any wise affected by the possibility that such misbranding may also be the subject of a Federal Trade Commission cease and desist order, or even by the fact that such an order has actually been entered.

Sections 201 (m), 304 (a), Federal Food, Drug, and Cosmetic Act.

Where a circular stated that the drug product "Nue-Ovo" was a competent and beneficial treatment for arthritis, and the libel charged that it was not, and that, therefore, the circular was false and misleading, there was no merit in the claimant's contention that the libel did not sufficiently charge that the circular was false and misleading.

Sections 201 (m), 304 (b), 502 (a), Federal Food, Drug, and Cosmetic Act.

J. Charles Dennis, U. S. Attorney, Seattle, Wash., Frank Hale, Assistant U. S. Attorney, Tacoma, Wash., and Wm. W. Barron, Attorney, Department of Justice, Washington, D. C., for appellant.

Chadwick, Chadwick & Mills, Howard P. Arnest, William S. Nash, Stephen F. Chadwick and Orville H. Mills, all of Seattle, Wash., for appellee.

Before DENMAN, MATHEWS and STEPHENS, Circuit Judges.

*[Lower Court Proceedings]*

MATHEWS, Circuit Judge: In the District Court of the United States for the Western District of Missouri, 143 packages of a drug called Nue-Ovo were proceeded against by appellant, the United States, on a libel for condemnation under § 304 (a) of the Federal Food, Drug, and Cosmetic Act,<sup>1</sup> 21 U. S. C. A. § 334 (a). On application of appellee, Research Laboratories, Incorporated, claimant of the 143 packages of Nue-Ovo, the proceeding was removed to the District Court of the United States for the Western District of Washington. In that court appellant was ordered to, and did, amend its libel. To the amended libel (hereafter called the libel) appellee filed exceptions, one of which was that the libel "fails to state facts sufficient to constitute a cause of action." This exception was sustained

and the proceeding was dismissed. From the order of dismissal this appeal is prosecuted.

*[Allegations of Libel]*

The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce. It does, however, state:

"That the said article [Nue-Ovo]<sup>2</sup> is misbranded in violation of the Federal Food, Drug, and Cosmetic Act \* \* \* in that the statements appearing in the labeling thereof, viz., in the circulars entitled 'What is Arthritis,' accompanying the said article are false and misleading in this, that all and singular of the statement therein and the whole thereof create the impression in the mind of the reader thereof that the said article is a competent

<sup>1</sup> Section 304 (a): "Any article of food, drug, device, or cosmetic that is \* \* \* misbranded when introduced into or while in interstate commerce \* \* \* shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, [with inapplicable exceptions]. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on

application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court \* \* \* shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

<sup>2</sup> The libel does not call Nue-Ovo a drug, but calls it an article. It nevertheless appears from the libel that Nue-Ovo is intended for use in the treatment of disease in man and hence is a drug within the meaning of the Act. See § 201 (g) of the Act, 21 U. S. C. A. § 321 (g). Appellee's brief concedes that Nue-Ovo is a drug.



treatment for arthritis and excite a feeling of hope and expectation in the mind of a sufferer from arthritis that the use and consumption of said article will be beneficial in treatment of said disease, whereas the said article is not a competent and beneficial treatment for arthritis. \* \* \*

"That on or about the 15th day of March, 1940, the said 143 packages, more or less, each containing 3 bottles of an article labeled in part 'Nue-Ovo' were shipped \* \* \* in interstate commerce from Chicago, Illinois, by Nue-Ovo, Inc., Chicago, Illinois, \* \* \* to Crown Drug Company, Kansas City, Missouri, and said article now remains unsold in the possession of the Crown Drug Company at Kansas City, Missouri.

"That the said circular accompanied said article while in interstate commerce, and thereafter, in the following manner, to-wit:

"That a shipment of circulars from Nue-Ovo, Inc., Chicago, Illinois, designated by title as 'What is Arthritis' (Exhibit A)<sup>3</sup> and containing the same printed words, letters and form, were received in interstate commerce by the Crown Drug Company of Kansas City, Missouri, at its warehouse \* \* \* in said city simultaneously with the said article; that the said circulars and the said shipment of 'Nue-Ovo' were placed, then and there, in the same room of the said warehouse for distribution to retail stores of the said Crown Drug Company at Kansas City, Missouri \* \* \*."

Thus, in substance, the libel states that 143 packages of Nue-Ovo and printed circulars containing false and misleading statements concerning Nue-Ovo were shipped in interstate commerce from Chicago, Illinois, to Kansas City, Missouri, and that all the packages and all the circulars were so shipped by a single shipper (Nue-Ovo, Inc.) to a single consignee (Crown Drug Company) and were by said consignee simultaneously received in interstate commerce.

[*Court's Holding on Issues*]

These statements must, for present purposes, be taken as true. Taking them as true, we hold that the circulars accompanied the packages and constituted their labeling within the meaning of the Act;<sup>4</sup> that, since the circulars were false and misleading, the packages were misbranded within the meaning of the Act;<sup>5</sup> that, since the circulars accompanied the packages in interstate commerce, the packages were misbranded while in interstate commerce within the meaning of the Act; and that, therefore, the packages—and, of course, their contents—are subject to condemnation.

The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

[*Discussion of Manufacturer's Contentions*]

Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article.<sup>6</sup> Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug, and Cosmetic Act is designed, to prevent

<sup>3</sup> Exhibit A—a copy of the circular entitled "What is Arthritis"—is attached to the libel. The gist of the circular is that Nue-Ovo is a competent and beneficial treatment for arthritis.

<sup>4</sup> Section 201 (m) of the Act, 21 U. S. C. A. § 321 (m), defines the term "labeling" as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

<sup>5</sup> Section 502 of the Act, 21 U. S. C. A. § 352, provides:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

<sup>6</sup> See footnote 4.



injury to the public health. *A. O. Andersen & Co. v. United States*, 9 Cir., 284 F. 542, 543; *United States v. 48 Dozen Packages of Gause*, 2 Cir., 94 F. 2d 641, 642.

It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled "What is Arthritis." The power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding

may also be the subject of a cease and desist order or even by the fact, if it be a fact, that such an order has actually issued.

There is no merit in appellee's contention that the libel does not sufficiently charge that the circular entitled "What is Arthritis" is false and misleading. The circular states, in substance and effect, that Nue-Ovo is a competent and beneficial treatment for arthritis. The libel charges that it is not, and that, therefore, the circular is false and misleading. No other charge is necessary.

[*Ruling*]

Order reversed.

### UNITED STATES v. 1232 CASES, MORE OR LESS, EACH CASE CONTAINING 24 CANS OF AMERICAN BEAUTY BRAND OYSTERS

United States District Court for the Western District of Missouri, Western  
Division. No. 907. February 28, 1942. 43 F. Supp. 749.

In a seizure action against oysters, based on shell content, there was no evidence to support the Government's contention that the shells had been added to the product while being processed.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Section 402 (a) (1) of the Act contemplates that there may be of necessity food products containing deleterious substances.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The provision as to tolerances in Section 406 does not apply where the deleterious substance inheres in the product and is not added.

Sections 402 (a), 406 (a), Federal Food, Drug, and Cosmetic Act.

Fragments of shell in oysters were held to be a deleterious substance, but Congress withdrew such foods from the adulterated class "if the quantity of such substance in such food does not ordinarily render it injurious to health." Shell fragments in the article proceeded against did not ordinarily render it injurious to health where the evidence showed that with the then known means it was impossible to free the product entirely from shell fragments, and that the claimant's processing operations were in accord with the best manufacturing practice.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Maurice M. Milligan, U. S. District Attorney, and Otto Schmid, Assistant U. S. District Attorney, Kansas City, Mo., for plaintiff.

R. W. Thompson, Gulfport, Miss., and Fred G. Mancuso, Kansas City, Mo., for claimant.

[*Nature of Proceeding*]

REEVES, District Judge: This is a proceeding by the process of libel to condemn an alleged adulterated food product. Such food consists of 1232 cases of oysters, each case containing 24 cans, marked "American Beauty Brand Oysters."

[*Basis for Condemnation*]

As a basis for condemnation, it is alleged by the Government that said article "contains shell fragments, many of them small enough to be swallowed and become lodged in the esophagus, and that said shell fragments are sharp and capable of inflicting injury in the mouth."



*U. S. v. 1,232 Cases American Beauty Brand Oysters**[Statutory Provision in Issue]*

The provision of the law invoked by the government is section 342, Title 21 U. S. C. A., and sundry subdivisions thereof. Said section provides, among other things, that:

"A food shall be deemed to be adulterated—

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; *but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.*"

*[Impossibility of Freeing Oysters from Shell Fragments]*

The claimant appeared to deny the averments of the libel and assert ownership of the product. The evidence in the case showed that in the processing of oysters for food there is a constant effort to eliminate shells and fragments thereof from the product. For this purpose many means and devices are used to reduce as nearly to a minimum as possible such shells and fragments in the product. The evidence, however, on behalf of both the government and the defense was that with present known means and devices it was impossible to free the product entirely from the presence of part shells and shell fragments. Moreover, it not only appeared, but it is a matter of common knowledge, that an oyster is a marine bivalve mollusk with a rough and an irregular shell wherein it develops and grows, and that, in the processing of the food product, it is necessary to remove this irregular, rough shell so far as that may be accomplished. The shells, therefore, are not artificially added for the purpose of growth or to aid in the processing operations.

*[Review of Evidence]*

The evidence on the part of the government was that parts of shell and shell fragments upon inspection were found in many of the cans taken from the article seized. Such parts of shell and fragments were exhibited at the trial.

There was evidence on behalf of the claimant that its processing operations were in accord with the best manufacturing practice and there was even some testimony that the means employed by it for the elimination of shell fragments were superior to the means employed by other processors en-

gaged in similar operations. The testimony on the part of the claimant further tended to show that within the Kansas City area over a period of ten years it had sold approximately 5 million cans of its product and that no complaint had ever been made concerning the presence of shell fragments. Claimant also proved that over 50 million cans had been processed by it and distributed in its trade territory and that no complaints had ever been made of the presence of part shells or shell fragments.

*[No Evidence To Support Addition of Shells]*

It seems proper at this point to comment that in this case involving considerable testimony there was no substantial controversy as to the facts and practically no difference of opinion as to the law. There was a contention by the government that the shells as a deleterious substance were added to the product while being processed. There was no evidence to support this contention.

*[Statutory Provision in Issue Construed]*

1. The excerpt from the statute heretofore quoted contemplates that there may be of necessity food products containing deleterious substances. No one who has had the experience of eating either fish or oysters is unfamiliar with the presence of bones in the fish (a deleterious substance) and fragments of shell in the oysters (also a deleterious substance).

The Congress, however, withdrew such foods from the adulterated class "if the quantity of such substance in such food does not ordinarily render it injurious to health."

*[Government's Contention Discussed]*

The evidence on both sides was that by the greatest effort, and in the use of the most modern means and devices, shell fragments could not be entirely separated from an oyster food product. The government, in its brief, quite aptly and concisely stated its point by using the following language:

"It is the character, not the quantity of this substance that controls its ability to injure."

This concession on the part of the government, properly made, upon the evidence removes the case immediately from that portion of the statute which says:



"\* \* \* such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

Since it is the "character, not the quantity of this substance that controls its ability to injure," as stated by the government, then in the view that it is impossible to eliminate shell fragments *in toto* from the product, the use of oysters as a food must be entirely prohibited or it must be found that the presence of shell fragments is not a deleterious substance within the meaning of the law and must be tolerated. To reject oyster products as a food is unthinkable. It would be as reasonable to reject fish because of the presence of bones. Even if a greater percentage of shells and shell fragments were found in claimant's product than in that of other processors, yet this fact, under the theory of the government, would not add to the deleterious nature of claimant's product. It should be stated, however, that there was no evidence that there was an excess of shell fragments in claimant's product over that of other processors. On the contrary, a preponderance of the evidence showed that the claimant's processing methods were superior.

*[No Testimony To Support Other Averments of Government]*

2. It does not seem necessary to discuss other portions of said Section 342 invoked by the government. It is charged in the libel complaint that other provisions of the statute were violated by substituting shell fragments for oysters, and that shell fragments had been mixed or packed with the oyster product so as to reduce its quality. There was no testimony to support these averments and so as to make applicable those provisions of the law directed against such acts.

*[Non-Applicability of Tolerance Section of Act]*

3. Counsel for both the government and the claimant, at the trial and in their briefs, discussed the question of the right to a tolerance regulation as provided by Section 346, Title 21, U. S. C. A. This provi-

sion is for tolerance of both poisonous and deleterious substances where the presence of such substance cannot be avoided. However, that section says:

"(a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 342 (a)."

Adverting to clause 2 of said section 342 (a), it reads as follows:

"\* \* \* or (2) if it (food) bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 346."

It will be seen at once that this provision does not apply where the deleterious substance inheres in the product and is not added. Further quoting from section 346, however, note this language:

"\* \* \* but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health."

Upon the concession made by the government in this case, even if the tolerance section could be construed to apply, it is not the quantity of the substance but its character "that controls its ability to injure."

*[Product Not Injurious to Health Because of Presence of Shell Fragments Therein]*

4. Upon the evidence in the case it must be found that the presence of shell fragments in the article sought to be condemned does not ordinarily render it injurious to health.

*[Conclusion and Ruling]*

Under the statute and upon the evidence the government is not authorized to condemn the article seized for the reason that the processed article does not offend against the food and drug law. The claimant, therefore, should have restored to it the articles seized and the libel should be dismissed. It will be so ordered.



UNITED STATES v. 29 BOTTLES, MORE OR LESS, IN DIFFERENT SIZES, OF AN ARTICLE OF DRUG LABELED IN PART "OCEAN-LAX", SHIPPED BY MINERALIZED FOODS, INC., BALTIMORE, MD.

United States District Court for the Eastern District of Pennsylvania. No. 166 of 1941.  
Filed March 4, 1942. 44 F. Supp. 317.

Whenever it appears that a seizure has been made, and a libel filed, in a district which is itself of "reasonable proximity" to the claimant's principal place of business, that fact alone constitutes good cause against removal.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The Eastern District of Pennsylvania was a district of "reasonable proximity" to the claimant's principal place of business, since the district court sat in Philadelphia, which was approximately one hundred miles from claimant's place of business.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Gerald A. Gleeson, U. S. Attorney for the Eastern District of Pennsylvania, for Libelant. Edward A. Kallick, Assistant U. S. Attorney, of counsel.

N. S. West, General Counsel, Baltimore, Md., for claimant. Messrs. White & Staples, C. L. Cushmore, Jr., of counsel.

*[Libel Charging Adulteration and Misbranding]*

BEN MOORE, District Judge: This is a suit by the United States of America under the Federal Food, Drug & Cosmetic Act of June 25th, 1938, to condemn twenty-nine bottles more or less of a product called "Ocean-Lax". The libel charges adulteration and misbranding. The articles were seized in the city of Philadelphia, in the Eastern District of Pennsylvania, in the hands of Thomas Martindale and Company, and are still in this District.

*[Motion to Remove to Another District]*

Motion has been filed by Mineralized Foods, Inc., claimant of the products seized, for an order to remove the case for trial to the District Court of the United States for the District of Maryland. The ground for the motion is that the claimant, Mineralized Foods, Inc., is a corporation having its principal place of business in the city of Baltimore, Maryland. The claimant relies upon the provisions of the act set out in Section 304 (a) (21 U. S. C. A. Sec. 334) of which the pertinent portion is as follows:

"In any case where the number of libel for condemnation proceedings is limited as above provided the proceedings pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the

seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

*[Interpretations of "Reasonable Proximity"]*

It is contended by the claimant that because its place of business is located in the District of Maryland and because the act provides that unless good cause to the contrary is shown by the Government it is entitled to have the Court specify a Court of "reasonable proximity" to its principal place of business as the place of trial, it therefore necessarily follows that a removal order should be entered, and that the District Court for the District of Maryland is the proper place to which the case should be removed. The Government contends on the other hand that a proper interpretation of the Act, particularly in view of its legislative history, does not permit the Court to remove the case to the district of claimant's residence; in other words that the term "reasonable proximity" must be held to exclude the claimant's own district.

*[Cities 100 Miles Distant Held Within Reasonable Proximity]*

I do not find it necessary to decide this point in passing upon the motion. The parties having failed to stipulate with reference to any district to which the case



should be removed, the Court's duty is to specify a district of "reasonable proximity" *unless good cause to the contrary is shown*. I am of opinion that whenever it appears that the seizure has been made and the libel filed in a district which is itself of "reasonable proximity" to the claimant's principal place of business, that fact alone constitutes good cause against removal. The Eastern District of Pennsylvania is a district of "reasonable proximity" to the claimant's principal place of business. The District Court for that district sits in the city of Philadelphia which is approximately one

hundred miles distant from claimant's principal place of business. It is imposing no hardship upon the claimant in this instance to require the case to be tried in the district where the libel is filed. It appears that the seized products are situated in this district and were in the hands of a person other than claimant when seized; and it is further stated by the Government that many of the witnesses are in this district.

Claimant's motion will be denied. An order may be prepared and entered in accordance with this opinion.

### UNITED STATES v. FIFTEEN CARTONS, MORE OR LESS, OF SEKOV REDUCER

United States District Court for the Southern District of Texas, Houston Division.  
Civil action No. 561. April 30, 1942. 45 F. Supp. 52.  
Affirmed, 139 F. 2d 197. See page 53.

Where the evidence clearly showed that "Sekov" was not a reducer, and the label of the product described it as "Reducer" and contained a picture of a woman with a slender figure, the labeling was held to be false and misleading.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

It was unnecessary to decide whether an order of the Federal Trade Commission rendered the product immune in a seizure action, since the order, findings, and conclusions of the Commission supported the contention of the Government that the labeling was false and misleading.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

"Sekov," containing thyroid, was held to be dangerous to health when used as prescribed on the label.

Section 502 (j), Federal Food, Drug, and Cosmetics Act.

Douglas W. McGregor, U. S. Attorney, and William R. Eckhardt, Assistant U. S. Attorney, of Houston, Texas; for plaintiff.

Harold E. Prudhon, of Los Angeles, Calif., and Baker, Botts, Andrews & Wharton (W. M. Ryan), of Houston, Texas, for defendant.

#### [Facts of Case]

KENNERLY, District Judge: This is a libel by the United States Government under the Federal Food, Drug and Cosmetic Act (Sections 301 to 392, Title 21, U. S. C. A.), to condemn Fifteen Cartons, more or less, of Sekov Reducer, a claimed remedy for obesity, found and situated in this District and Division, alleged to be misbranded within the meaning of the Act, and to have been shipped on or about May 24, 1941, in Interstate Commerce by Sekov Corporation, Hollywood, California, to Sekov Reducing Studio, Houston, Texas, for sale

by such Studio. The Sekov Corporation (for brevity called Claimant) is here, claiming such articles, denying the allegations of the Government, and contending for immunity here because, as it says, the Federal Trade Commission in a proceeding before it has heretofore assumed jurisdiction of and decided the questions here involved.

It has been stipulated that the articles sought to be condemned were shipped in Interstate Commerce for sale in this District and Division as alleged, that they have been seized, and the Complaint and Order



*U. S. v. Fifteen Cartons Sekov Reducer*

in the proceedings before the Federal Trade Commission are in evidence. Thus we are brought at once to the questions to be determined.

1:—The Government complains with respect to such articles as follows:—

"Said article is misbranded in violation of the Act of June 25, 1938, known as the Food, Drug and Cosmetic Act, in that the statement on the carton 'Reducer' and the design of a slender female figure are false and misleading, since they imply that the article is a safe and appropriate treatment for the reduction of weight, when in fact the article is not such a safe and appropriate treatment but is a dangerous drug and does not constitute an effective agent in reducing weight."

This complaint is bottomed on that part of the Act reading as follows (Section 352 (a), Title 21, U. S. C. A.):—

"A drug or device shall be deemed to be misbranded:  
\* \* \*

"If its labeling is false or misleading in any particular."

On the outside of the container or package of "Sekov" are these words:—

"SEKOV

Trade Mark Reg. U. S. Pat. Off.

REDUCER

(Then follows a picture of a woman with a slender figure)

Manufactured for—Packed by  
6404 Hollywood Blvd.—Sekov

Corporation—Hollywood, California."

"Sekov" comes in and is to be taken in two capsules, stated on the label to contain and which the evidence shows do contain ingredients as follows:—

"No. 1 Capsule:—	No. 2 Capsule
Active Ingredients	Active Ingredients
Thyroid, U.S.P. 1.87 Gr.	Rhubarb Powder
Whole Ovarian	Asafetida
Whole Pituitary	Cascara Sagrada
Alolin	Oleoresin Ginger
	Alolin—Bile Salts."

[Labeling Found False and Misleading]

I find the labeling false and misleading. The evidence clearly shows that "Sekov" is not a reducer, i. e., that it is not a remedy for obesity and will not reduce the weight or figure of a heavy or stout woman to the slender proportions shown in the picture on the container.

[Whether Booklets Are Part of Label Held Immaterial]

It is shown that the Sekov Reducing Studio, Houston, was furnished by Claimant with a supply of printed booklets, the title of which is "Sekov, A Path to Slenderness." These booklets were shipped to the Studio in Interstate Commerce and kept on hand by the Studio in Houston and sent or delivered to persons making inquiry by mail or in person with respect to "Sekov." The evidence is not convincing that one of these booklets went to every purchaser of "Sekov." Citing *United States v. Research Laboratories, Inc.* (U. S. C. A. Ninth, decided February 24, 1942, — Fed. (2d) —), Claimant says that such booklets under Section 201 (m) of the Act (Section 321 (m), Title 21, U. S. C. A.) must be considered as part of the label. Citing *United States v. 59 Tubes*, 32 Fed. Supp. 960, the Government combats this view. Which is right, I do not find it necessary to decide, because the booklets, if construed as part of the label, do not help Claimant, but support the Government's contention. The front outside cover of the booklets introduces "Sekov" as "A Path to SLENDERNESS" and shows the same picture of a slender woman shown on the container. It is then said, "A Reducing Formula", "No Rigid Diet," "No Strenuous Exercises". The back outside cover and the inside of the booklets contain similar statements, also two pictures of a very stout woman and a very slender woman, purporting to show "before" and "after" use of "Sekov." They also contain four strong testimonials from women, praising "Sekov" as a flesh reducer, one claims the writer was reduced from 212 to 128 pounds, another from 149 to 130 pounds, another from 164½ to 135 pounds, and still another from 145 to 123 pounds. There are some rather obscure statements in the booklets that "Sekov" contains thyroid and is a treatment for obesity only when used by persons suffering from hypothyroidism (lack of thyroid), but the booklets, considered as a whole, strongly affirm that "Sekov" is a reducer and a cure for obesity generally.

Whether the label on the container is considered alone or in connection with the booklets, it is false and misleading within the meaning of the Act.



[Federal Trade Commission Order Supports  
 Government Contention]

Standing on *George H. Lee & Co. v. Federal Trade Commission*, 113 Fed. (2d) 583, Claimant says the Order of the Federal Trade Commission renders it immune here. The Government combats this view. I find it unnecessary to decide the question thus raised, because a fair construction of the Order of the Commission<sup>1</sup> and the Findings of Fact and Conclusions of Law therein supports the contention of the Government, and the finding here that the labeling is false and misleading.

[Dangerous Dosage Found]

2:—The Government, in its Libel, also complains with respect to such articles as follows:—

“Said article is further misbranded in that it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, namely, (on the carton): ‘30—No. 1 Capsules THIRTY DAYS SUPPLY \* \* \* No. 1 One Capsule Before Noon Meal.’ This allegation is based on the fact that the capsules when taken in accordance with the suggested directions will supply a dangerous amount of thyroid.”

This complaint is bottomed on that part of the Act reading as follows (Section 352 (j), Title 21, U. S. C. A.):—

“A drug or device shall be deemed to be misbranded:

\* \* \*

(j) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof”.

The dosage and directions for taking “Sekov” are found on the container or cover of the package. On the outside of the container, there are these directions:—

“(30—No. 1 Capsules) Thirty Days Supply (15—No. 2 Capsules). Price \$5.50.

Adequate directions for use on inside cover of package.”

On the inside of the package or container, there are found these directions:—

“No. 1—One Capsule before Noon Meal (Preferably half to one hour before).

Not to be used by persons suffering from hyperthyroidism.

No. 2—One Capsule Every Other Night (Just before retiring).

Important not to be used when abdominal pain (stomach ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.”

<sup>1</sup> A part of the Order of the Commission is as follows:—

“The aforesaid statements, claims, and representations used and disseminated by the respondents in the manner above described are grossly exaggerated, misleading and untrue. In truth and in fact, said preparation advertised and known as ‘SEKOV REDUCER’ and as ‘SEKOV’ is not a scientific treatment for obesity when administered without a thorough medical examination and without scientific care and observation, and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. Obesity may be due to several causes, including the dysfunctioning of the pituitary gland and to excess intake of food, in which cases the use of said preparation will be improper and ineffective. Said preparation will not guard the health of the user and does not act on a corrective principle for the reason that the effect of the intake of thyroid accelerates the rate of metabolism whereby the tissues, especially fatty tissues, are burned more rapidly than is normal, and such a process may be dangerous and may be injurious to the health and life of the user unless the extent of such process is carefully coordinated to the exact needs of the person suffering from hypothyroidism. The use of said preparation is a harsh or strenuous method of reducing for the reasons herein set forth.

Said preparation does contain cathartics and dangerous drugs in that Capsule No. 1 of said preparation contains rhubarb, cascara sagrada, aloin and bile salts, all of which are cathartics, and all of which tend to dehydrate the body tissues. In addition said preparation contains the dangerous drug, extract of thyroid. Said preparation is not made for reaching the glands or nourishing the glands whose faulty function is the cause of most overweight. The only gland substances in said preparation are whole ovarian substance, whole pituitary substance and thyroid substance, and the effect of thyroid gland substance is to supply thyroxin to the system but not to rejuvenate the thyroid gland. Said preparation does not regulate the action of the glands gently and gradually or at all. The use of said preparation, although it may result in taking off fat by accelerating the rate of metabolism, may seriously weaken the body and the organs of the body, including the heart. Said preparation is not effective in reducing practically all cases of overweight for the reason that the drug extract of thyroid is effective only in the treatment of obesity in cases in which the patient is suffering from hypothyroidism. Most overweight is caused by excessive intake of food. Said preparation does not accomplish reduction of weight or fat by normalizing the body.”



*U. S. v. 45<sup>2</sup>/<sub>3</sub> Dozen Packages "U-X Improved Shaving Medium"*

The evidence supports and compels a finding, and I find, that "Sekov" is dangerous to health when used in the dosage or with the frequency or duration prescribed in the quoted directions on the label, and this is true whether the patient is or is not suffering from hyperthyroidism or from hypothyroidism.

In the hereinbefore mentioned booklets which Claimant says must be considered as a part of the directions, it is said:—

"Sekov contains Thyroid and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. (Lack of Thyroid.)

We recommend that you consult your physician to determine the cause of your overweight as the use of Thyroid by a person not deficient in Thyroid may result in serious or irreparable injury to the health of the user."

If, as Claimant contends, the booklets must be looked to as part of the label, there is no change in the findings. I do not think Claimant's case is helped when the booklets are considered as a whole.

*[Effect of Federal Trade Commission Order]*

The question arises again as to the effect here of the Order of the Federal Trade Commission in evidence and upon which Claimant relies upon for immunity. The Order contains findings that "Sekov" is not a scientific treatment for obesity as claimed, when administered without a thorough medical examination, and without scientific care and observation of the patient, and that it constitutes a treatment for obesity at all only when used by persons suffering from hypothyroidism. And that it may be dangerous and may be injurious to the health and life of the patient unless carefully coordinated to the exact needs of the person suffering from hypothyroidism. If, as Claimant insists, this Court is bound by such Findings, Claimant's case is not helped.

*[Articles Condemned]*

It is not necessary to discuss other questions raised by the pleadings. From what has been said, it follows that the Government is entitled to Judgment, condemning such articles.

**UNITED STATES v. 45<sup>2</sup>/<sub>3</sub> DOZEN PACKAGES, MORE OR LESS, OF AN ARTICLE LABELED IN PART "U-X IMPROVED SHAVING MEDIUM"**

United States District Court for the Southern District of New York.  
No. A124-221. May 21, 1942. 46 F. Supp. 112.

A seizure action had been transferred for trial twice, the second time to the district where the claimant had his principal place of business. On the Government's motion to transfer the case back to the district to which first transferred, it was held that the United States Attorney for such district had consented to the second transfer, that such consent was in effect a stipulation, and that such transfer was consequently permissible.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Mathias F. Correa, U. S. Attorney, and Joseph C. Kenney, Assistant U. S. Attorney, for libellant.

Mock & Blum, for claimant.

*[Government's Contention]*

GODDARD, District Judge: The United States Attorney for the Southern District of New York moves for an order transferring this proceeding back to the United States District Court of Connecticut. It is urged in support of this motion that the case had been transferred from the United States District Court for the Western District of Pennsylvania to the United States District Court of Connecticut, and that under the

provisions of the Federal Food, Drug and Cosmetic Act [21 U. S. C. A. § 334(a)] the Connecticut Court is without power to transfer the case a second time, or to transfer the case to a district where the claimant has his principal place of business.

*[Claimant's Contention]*

Claimant contends that the order transferring the case to this court had been consented to by the United States Attorney for



the District of Connecticut, and, accordingly, such transfer was permissible under the statute. I agree with this contention. The statute specifically provides that a proceeding "pending or instituted" shall on application of the claimant be removed to any district agreed upon by stipulation between the parties. The consent of the United

States Attorney for the District of Connecticut was in effect a stipulation. Nowhere is it provided that by stipulation a proceeding may be transferred only once, and then only to a district where the claimant does not have his principal place of business.

[*Ruling*]

Motion denied. Settle order on notice.

---

**UNITED STATES v. 893 ONE-GALLON CANS, MORE OR  
 LESS, 37 FIVE-GALLON CANS, MORE OR LESS,  
 OF AN ARTICLE LABELED IN PART  
 "BROWN'S INHALANT"**

United States District Court for the District of Delaware. No. 1529 in  
 Admiralty. May 26, 1942. 45 F. Supp. 467.

The legislative history of the Act, and the language of the seizure section, make it manifest that when an article is seized the issue of adulteration or misbranding must be determined by the court, and that destruction or release may be had only after entry of a decree of condemnation.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

Stewart Lynch, U. S. Attorney, and William Marvel, Assistant U. S. Attorney, both of Wilmington, Del., for the Government.

Harold B. Howard of Wilmington, Del., for Alvin J. Timmons, Gerald A. Timmons and Louis J. Timmons, co-partners, trading as A. J. Timmons & Sons, for claimants, and Edgar W. Brown, the manufacturer.

[*Facts of Case*]

LEAHY, District Judge: A libel was filed which sought seizure and condemnation of certain cans containing poultry medicine. The articles were shipped from Pennsylvania into Delaware. The libel charges misbranding of the product within the meaning of the Federal Food, Drug and Cosmetic Act of June 24, 1938.<sup>1</sup> The marshal made seizure. The claimants, who were in possession of the articles, filed an answer denying the property was misbranded. The manufacturer, Edgar W. Brown, an individual engaged in business under the name of "Brown's Poultry Products Co.," in Lancaster, Pennsylvania, was permitted to intervene on May 21, 1942, to defend the labeling on his own behalf. In the order permitting the intervention, there was a provision directing that the property be discharged from seizure and delivered to the claimant upon the claimant's filing bond; and that the claimant should not sell said property unless and until the labels

were removed. The reasons offered to the Court, in support of such procedure, was that it was admitted the contents of the cans were not deleterious and that merely the labels came within the prohibition of the statute. On May 26, 1942, the Government moved to amend the precipitous order of May 21, 1942, by striking out those portions which permitted a return of the seized property.

[*Procedure in Admiralty*]

In opposing the Government's motion, both the manufacturer and claimant assert that as this is a cause in Admiralty, they should be allowed to have possession of the property before final hearing and decree by filing an appropriate bond in view of the fact that the statute provides that the procedure under Section 334 (b) "shall conform, as nearly as may be, to the procedure in Admiralty; . . .". Especially is this so in view of the fact that the Government admits, they argue, the contents of the cans

---

<sup>1</sup> 21 U. S. C. A. 352 (a).



*U. S. v. 893 One-Gallon Cans "Brown's Inhalant"*

are not harmful. The Government contends that there can be no release of seized property under the statute until "after entry of the (final) decree"<sup>2</sup> of condemnation. A search discloses no decision dealing with the precise question raised.

Sec. 334 (b) does state that the procedure "in cases under this section shall conform, as nearly as may be, to the procedure in Admiralty." The argument of the claimants that the application of the Admiralty Rules should control the procedure as to release of seized products finds no support when we examine the Admiralty Rules. Rule 11 deals with release of perishable goods. Obviously this rule can hardly apply to non-perishable goods seized under Sec. 334 (d). Rule 12 relates to the release of a vessel to

the claimant upon the filing of bond to protect the claim of libellant.<sup>3</sup> Hence, it appears that there is no apposite Admiralty Rule or traditional practice upon the basis of which goods may be released prior to decree of condemnation.

## [Legislative History of Sec. 304]

The legislative history of the present statute throws some light on the procedure intended by Congress. If we turn to Sec. 10 of the Federal Food and Drugs Act of 1906,<sup>3(a)</sup> it likewise appears that the release and delivery of the articles to the owners is only after the entry of a decree of condemnation.<sup>4</sup> The language of the various bills considered by Congress from 1933 to 1937 remained unchanged with respect to the release of articles and the giving of bond.<sup>5</sup>

<sup>2</sup> 21 U. S. C. A. § 334 (d): "Any food, drug, device, or cosmetic condemned under this Section shall, after entry of the decree, be disposed of by destruction or sale as the Court may, in accordance with the provisions of this section, divert and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such articles shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the Court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Chapter under the supervision of an officer or employee duly designated by the Administrator and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under Section 344 or 355, be introduced into interstate commerce, shall be disposed of by destruction."

<sup>3</sup> For an analogous situation, involving seizure of a vessel for forfeiture, see *The Pietro Campanella*, 41 F. Supp. 656, where the court said:

"It is pointed out for the claimant that the statutes of the United States and the practice in Admiralty do not permit the surrender of a libelled ship to the libellant except after formal decree of condemnation; and the analogous proceedings for forfeiture of other property are generally to the same effect."

<sup>3(a)</sup> 21 U. S. C. A. § 14: "... seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said Court may direct, and the proceeds thereof, if sold, less the legal

costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided*, however, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District or insular possession, the Court may by Order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in Admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States".

<sup>4</sup> Three cases decided under the 1906 statute passed upon the release of goods to claimants. In *United States v. Nine Barrels of Butter*, 241 F. 499, the application for release was not made until after the entry of a decree of condemnation. In *A. O. Andersen & Co. v. United States*, 9th Cir. 284 F. 542, it would seem the court assumed the necessity of a prior decree of condemnation, before release. In *United States v. Two Cans of Oil of Sweet Birch, etc.*, 268 F. 866, it appeared that the claimant moved for release of the product before decree; but if I have failed to read the cases correctly and the motion was made, in fact, after decree, it would seem to make little difference as the court simply held that the motion was one addressed wholly to the court's discretion and the court declined to exercise it in favor of the claimant.

Thus, no Court, as far as I have been able to find, has held specifically that release may be had before decree, or that release may only be had after decree.

<sup>5</sup> S. 1944, 73 Cong. 1st and 2d Sess.; S. 2800, 73 Cong. 2d Sess.; S. 2800, 73 Cong. 2d Sess.; S. 5, 74th Cong. 1st and 2d Sess.; S. 5, 75th Cong., 1st and 3d Sess.



The various Senate Reports as well as the hearings had on the several proposed bills, make it manifest to me that Congress understood the procedure looked to the entry of a decree of condemnation before release of the seized articles.<sup>6</sup>

Not only is the legislative history of Sec. 304 helpful in determining its meaning, but a mere examination of the statute makes it clear that (1) an article may be proceeded against by libel when it is adulterated or misbranded; (2) once such an article is seized the issue of adulteration or misbranding must be determined by the Court; (3) if the article is neither adulterated nor misbranded, it is released to the claimant;

but (4) if it is adulterated or misbranded it may be disposed of only as provided by Sec. 304 (d). Destruction or release may only be had after decree.

*[Order Permitting Return of Goods  
to Claimant Stricken]*

I reject the contention of the claimants that the articles may be released prior to judicial determination of whether they were misbranded. Accordingly, the motion of the Government to amend the Order of May 21, 1942, is granted. An Order may be submitted striking out those portions of the May 21st Order which permitted a return of the seized goods.

### UNITED STATES v. 998 CASES OF TOMATO PUREE

United States District Court for the Western District of Michigan. September 21, 1942, and April 21, 1943. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7850) Issued January 1946.

In a seizure action instituted against tomato puree on the ground that it consisted in whole or in part of a decomposed substance, it was held that condemnation proceedings under Section 304 (a) are essentially civil and are not designed to obtain information for use in evidence against the owner, and that the Fourth Amendment to the Constitution is inapplicable.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

On motion of the claimant to compel answer to interrogatories, it was held that the first interrogatory, as to whether the goods consisted of decomposed products at the time of shipment, was wholly immaterial.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

While it has been held that Admiralty Rule No. 51 as to interrogatories should be construed as broadly as Rule 33 of the Federal Rules of Civil Procedure, the better rule is that interrogatories may not be used to examine the opposite party as to evidence upon which the other will rely to support his own case.

Sections 304 (a), 304(b), Federal Food, Drug, and Cosmetic Act.

*[Order To Be Entered Denying Motion To  
Quash Warrant]*

FRED M. RAYMOND, District Judge: It being the view of the court that proceedings for condemnation under Section 304 (a) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A., Section 334) are essentially civil and are intended for protection of the lives and health of the public, and that they are not designed to obtain information for use in evidence against the owner and that therefore the Fourth Amendment to the Constitution is inapplicable (see *United States v. Eighteen Cases of Tuna Fish*, 5 F. (2d)

979; *United States v. B. & M. External Remedy*, 36 F. (2d) 53; *Boyd v. United States*, 116 U. S. 616; *North American Cold Storage Co. v. City of Chicago*, 211 U. S. 306; 15 Ann. Cas. 281; 56 C. J. 1166; 25 C. J. 1173; 22 Am. Jur., Food, Section 81), an order may be entered denying the motion of Ladoga Canning Company to quash warrant and seizure, and for return of goods.

[On October 5, 1942, the claimant filed exceptions to the libel, which were dismissed by the court on January 14, 1943, and subsequently, on or about January 26, 1943, the claimant filed an answer denying that the

<sup>6</sup> For the various Senate Reports and the hearings on the proposed bills, see Dunn, Federal

Food, Drug, and Cosmetic Act (1938) pp. 46, 61, 102, 206, 642, and 1263 et seq.



product was adulterated and submitted certain interrogatories. The claimant's motion for an order compelling answers to the interrogatories was denied in the following opinion of the court, dated April 21, 1943:]

[*Order Compelling Answers to Interrogatories Filed*]

FRED M. RAYMOND, District Judge: In proceedings in admiralty for seizure and destruction of alleged adulterated tomato puree introduced into interstate commerce, claimant has filed a motion for an order compelling answers to interrogatories. These interrogatories seek disclosure of the following information: (1) the extent to which the seized goods consisted of decomposed tomato products at time of shipment; (2) the number of cans taken out of shipment and their contents examined, with the can marks of each can; (3) the number of cans found to contain decomposed products, with the can mark of each can; (4) the nature of the test or examination made of the contents of each can; (5) the result of the test or examination made of the contents of each can with the can mark of each such can.

[*Main Issue Is Whether or Not Food Is Adulterated*]

The issue before the court under the the statute is whether or not the food was adulterated when introduced into or while in interstate commerce. For this reason, the first interrogatory, as to whether the goods consisted of decomposed products at the time of shipment is wholly immaterial.

[*Remaining Interrogatories Objectionable*]

The remaining interrogatories, in substance, seek to obtain from the libelant evidence upon which it will rely to support its own allegations, and are objectionable for this reason. In the case of *Coronet Phosphate Co. v. United States Shipping Co.*, 260 F. 846, Judge Learned Hand said (Page 849):

"\* \* \* Interrogatories in the admiralty serve two purposes, to amplify the pleadings of the party interrogated, and to procure evidence in support of the libel or defense of the party interrogating. *Bock v. Int. Nav. Co.* (D. C.) 124 Fed. 711; *The Baker Palmer* (D. C.) 172 Fed. 154. They should not, however, be used merely to fish into the evidence which

the party interrogated may produce in support of his own allegations. This limitation upon discovery has remained even in the most modern rules of procedure. A party is of course entitled to know whether his opponent admits the truth of his own allegations, and how far, so as to avoid unnecessary preparation for trial. He is not entitled to know what evidence his adversary will produce to prove the adversary's allegations, and what evidence he must himself produce to overcome the case so made. The result will, of course, be, as it has been in the past, that he must go to trial somewhat in the dark as to what he must meet. The pleadings are intended to advise him of that, and interrogatories are proper to reduce those allegations to very specific form. They should be encouraged for that purpose, but so far as they call upon the pleader to go further, and give, not only the details of his allegations, but the evidence by which he means to prove them, they are liable to abuse. If there develop on the trial a case of genuine surprise, the court, especially where there is no jury, has ample power to protect the party surprised."

[*Use of Interrogatories Limited*]

While it has been held that admiralty rule No. 31 as to interrogatories to parties should be as broadly construed as federal rule 33 touching disclosure of an adversary's case (see *The Exermont*, 1 F. R. D. 574; *Citro Chemical Co. v. Bank Line Limited*, 1 F. R. D. 638), the better rule is that interrogatories may not be used to examine the opposite party as to evidence upon which the other will rely to support his own case (*Jensen v. Sinclair Nav. Co.*, 58 F. (2d) 407; *Cargo Carriers v. The Prospect*, 2 F. R. D. 519; *The Arthur Connors*, 35 F. Supp. 775).

[*Order To Be Entered Denying Motion for Order Compelling Answers to Interrogatories*]

An order will be entered denying the motion filed February 26, 1943.

[The claimant having withdrawn its answer, the court, on November 18, 1944, entered a judgment of condemnation. On November 20, 1944, it was ordered that certain portions of the product identified by certain code numbers be destroyed by delivery to a Federal institution, for use as animal food, and that the remainder be released to the claimant.]



## UNITED STATES v. 667 CASES OF CANNED HERRING ROE

United States District Court for the District of Maryland. November 2, 1942.  
Notices of Judgment Under the Federal Food, Drug, and Cosmetic  
Act, Foods (No. 8917) Issued February 1947.

Seizure proceedings were instituted against herring roe alleged to consist in whole or in part of a filthy substance because of the presence of the viscera, stomach, intestines and partially digested matter. The district judge did not feel that he could limit the word "filthy" in Section 402 (a) (3) absolutely by saying nothing would be filthy unless it was definitely unhealthy. Where it was admitted that the alleged filthy substance was in no way harmful to health but merely such as to make a food product unattractive in appearance to the consumer, the district judge doubted whether the meaning of "filthy" was gratified by the latter condition.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The Government had not sufficiently established by a preponderance of the evidence that the so-called extraneous matter was filthy in the proper application of the term in the context in which it is included in the law.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

CHESTNUT, District Judge: Gentlemen, I would have very much preferred to have submitted this case to a jury because they represent a cross-section of the public in determination of the facts. And I think a decision is much more satisfactory if made by a jury in such cases than if made by a single judge. However, when neither side wants a jury trial, the Judge has to solve the problem of determining the facts. Now, it is also my duty under Rule 52 of the Federal Rules of Civil Procedure to make a finding of facts and conclusion of law in these non-jury cases.

*[Condemnation Proceeding]*

I understand this is not a criminal prosecution but a condemnation proceeding by libel of alleged improper food products and the precise issue is whether the food product which is involved in an interstate shipment was adulterated because it contained filthy matter, which is specified in the bill of particulars to have been in cans of herring roe, some part of the viscera and stomach and intestines and other digested matter in some of the herring, under U. S. Code, Title 21, Section 342.

*[Context Involved]*

I think to get the full force of the meaning of the Act of Congress, you must bear in mind, of course, that it is part of the Food, Drug, and Cosmetics Act of 1938, and we should look at the context in which the particular sentence or phrase is included. The heading of Section 342 is "Adulterated food". The provision is: "A food shall be

deemed to be adulterated—". Then there is a heading "Poisonous, unsanitary, etc., ingredients", and the Section continues:

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 346; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."

*[Meaning of "Filthy"]*

Now, it is perfectly obvious to the reader of that section that the whole gist of the matter looks to the health of the consuming public and, therefore, while the word "filthy" is rather a vague term to the extent of its whole meaning, yet in the context in which we find it, it seems to me that it was intended to be used in the sense of its effect on human beings as a food or with relation to food. I do not feel that I could limit it



absolutely and sharply by saying that nothing would be filthy in the sense of this statute unless it is definitely unhealthy but where you have a situation in which it is admitted that the alleged filthy substance is in no way harmful to health but merely such that when contained in a food product, the latter is made unattractive in appearance to the consumer, I doubt very much whether the meaning of "filthy" as contained in this section is gratified by that latter condition.

The word "filthy" is, perhaps, literally broad enough to cover the contentions here made by the Government as to just what it does mean. I read from Webster's International Dictionary:

"Filthy means defiled with filth, whether material or moral; nasty; disgustingly dirty; polluting; foul; impure; obscene. Secondary meaning: disgraceful; disgusting; low", and then I turn to Corpus Juris as a handy definition from a legal viewpoint of "filthy" and find it is defined as "Containing or involved in filth; contemptible; defiled by sinful practices; foul; dirty; low; mean; morally foul; nasty; noisome; polluted; scurvy; that which is nasty, dirty, vulgar, indecent, offensive to the moral sense; morally depraving and debasing."

[*Problem Involved*]

Now, our problem in this case is to determine whether the inclusion in some of these cans of herring roe, which were seized for condemnation, or part of the viscera, stomach, intestines and partially digested matter therein corresponding to it are included within the meaning of the word "filthy" as contained in this context.

[*Similar Case*]

Now, with regard to the facts of the case, I find that the facts are so almost exactly parallel to those stated by Judge Pollard in this case that is reviewed in the Federal Security Agency Bulletin of December, 1940, that I think it unnecessary to review the facts of this case at any great detail. The case referred to is *United States v. 896 and Other Numbered Cases of Herring Roe*, tried in the United States District Court for the Eastern District of Virginia at Richmond in 1940. That was a case which was in all respects materially parallel to this case except that here the interstate shipment which was seized was seized in Baltimore while in transit from Reedville, Virginia, to New York, and what was seized was 667 cases of

herring roe which represented more than a majority of the 1,015 cases constituting the total pack of the Reedville Company during 1942. The amount seized at market values apparently was over \$3,000 while the total market pack for the year would only have been about \$5,000, as I recall the figures. That, of course, is a very heavy seizure for a condemnation, and it seems to me that it at least justifies the requirement that the Government should quite clearly prove its case where the consequences are very material like that to the claimant of the goods.

[*Question for Determination*]

Now, after all, it is necessarily a jury question here as to what I find from the testimony of the Government as opposed by the testimony of the defendant. With the burden of proof being on the Government in this case to prove its case by a preponderance of the testimony, the question is whether I find from a preponderance of the testimony that the shipment contained filthy matter as particularized in the Bill of Particulars.

[*Evidence of Filth Not Sufficiently Established*]

Now, without going into further elaboration and detail, my conclusion in this case is that the Government has not sufficiently established by a preponderance of the evidence that the so-called extraneous matter was filthy in the proper application of that term in the context in which it is included in the law. I will say, however, in this case, as I have said in many of these Food and Drug Act cases, that I think the Act should be considered a very great improvement on the former Act and that the general administration of the Act by the Food and Drug Administration is very materially important and desirable and advantageous for the consumers of food and drug products. We have tried quite a number of these cases in this Court and very generally the result has been, I think, a justified finding in favor of the Government.

In this particular case, I do not feel that that should be the result. As I say, I think it is not properly found in this case that what we find here, undesirable as it may be from the standpoint of efficiency in merchandising, I do not think it goes to the extent of justifying a condemnation of this shipment that was seized.



*[Contents Not Injurious to Health]*

The important thing, of course, is that it is admitted by the Government that the unattractive contents of the cans, which certainly did not average more than about two per cent at most, was in no way injurious to health. The most you can say about it is that it rendered the product unattractive and in that sense only is it said to be filthy.

It is true that some of the representatives of the Food and Drug Administration say that that means to them that the article was filthy by virtue of the extraneous matter, but I think that is a too expanded definition of the word "filthy" as it is used in the Food and Drug Act.

Now, as I say, I think the general administration of the Act is very helpful to the public and very often helpful to the factories and food producers, and the impression was made on my mind that a greater care in the segregation of the viscera of the fish from the roe could well be striven for by the manufacturer in this case. At the same time, I am not prepared to say that the failure to make a complete separation condemns the article as a filthy thing.

*[Foreign Matter]*

I would also point out in that connection this important thing in the administration of the Food and Drug Act. The health of the public is the main thing, of course, we are looking at. That is of most importance with reference to foods. Now, "filthy" is a term of uncertain application. When food is manufactured under conditions where something that is foreign to the food product that is being worked upon is injected into the food product to be sold to the consumer, that, I think, is very definitely wrong. For instance, some months ago we had one or two of these cases where candy manufacturers had their goods seized on the ground that they allowed the candy to be exposed in their factories at night to the presence of rats or mice and the rats or mice would leave their excreta upon the candy. That, obviously, falls within the meaning of "filthy". It is the kind of thing that not only is repellent to a person who is told that such a thing existed with regard to the candy manufacturer, but nobody would be likely to say from a bacteriological standpoint that it might not be very definitely injurious to health. So in the case of prosecution some two or three years ago of crab meat packers down on the Eastern

Shore. The testimony was that the employees who picked with their hands the meat from the shell of the crab were not clean in their habits and were not required to wash their hands after going to the lavatory, in consequence of which it was alleged by the bacteriologists in a particular case that there were portions of human excreta in the canned product. Now, that case was tried before a jury and the jury found a verdict in favor of the Government, and I could not say that it was an improper verdict, although I think there was a motion for a new trial in the case, so whether the foreign substance which is alleged to be filthy is a really foreign substance and not a part of the whole operation of packing parts of the fish and getting along with the roe some parts of the viscera attached to the roe simply by virtue of lack of adequate care in making the separation, it seems to me there is a vast difference between the two kinds of foreign matter. In the case we have here, the matter that is included and alleged to be filthy is not foreign to the fish. It is at most a part of the fish which is not completely separated from the roe, while in the other case the foreign substance is something which is brought in quite unnecessarily and should undoubtedly be eliminated and could have been eliminated with care.

*[Unattractiveness]*

Here I am impressed with the testimony of the defendant to the effect that no matter how much care is used, it is nearly always likely that some hidden parts of the viscera of the fish may be included. Take, for instance, a deviled crab. It is very disagreeable to some people in eating a deviled crab to get particles of the shell of the hard crab which have not been eliminated by the cook in preparing it, but no one could say that it is filthy or makes the deviled crab filthy. It makes it unattractive and unpleasant for some people in eating but it can hardly be said to be filthy, so when you have the delicate surgical operation of separating the small roe of a small herring, weighing six to eight ounces, from the surrounding membranes or tissues of the stomach or viscera, it is a delicate operation which often leads to inadequate separation but that is not an injection of extraneous and foreign matter into the product. It is simply a lack of care in separating the roe from the rest of the fish.



Now, we have nothing here to the effect that the substance is decomposed or is injurious to health, but simply that it is unattractive. I think the witness, Mr. Hines, from Virginia, says it very definitely affects the grading for the purpose of commercial sale or the proper grading of the product for public sale, but it does not affect the health of the public.

*[Verdict for the Claimant]*

Now, that is the view I have of this particular case. Therefore, the verdict is for the claimant. If you want any judgment entered, well and good. If you want a more detailed finding of fact, I will be very glad to make it if you think it necessary.

[In accordance with the court's opinion, the libel was dismissed and the product released to the claimant.]

---

**UNITED STATES v. 108 BOXES OF CHEDDAR CHEESE**

United States District Court for the Southern District of Iowa. November 30, 1942. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 5478) Issued January 1945.

In a seizure action against cheese alleged to be adulterated under Section 402 (a) (3) and (4), the claimant filed a motion for a more definite and specific statement. The question of whether such an order should be entered was governed by the Rules of Civil Procedure of the court and not by the state law.

Sections 304 (a), 304 (b), 402 (a), Federal Food, Drug, and Cosmetic Act.

While the court has some discretion as to whether such an order should be made, it is generally held that such information is only to be furnished by discovery as provided in the Rules of Civil Procedure.

Sections 304 (a), 304 (b), 304 (c), Federal Food, Drug, and Cosmetic Act.

Since the claimant could obtain the information requested, insofar as it was in the possession of the attorneys for the Government, by the procedure authorized under Rule 33 of the Rules of Civil Procedure, and other rules of discovery, the motion for a more specific statement should be overruled.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

*[Motion for More Specific Statement]*

DEWEY, District Judge: The above entitled action came on for hearing in open court at Des Moines, Iowa, on the 21st day of November, 1942, on the intervening claimant's motion for more specific statement.

*[Information Obtainable]*

The question of whether such an order should be entered is governed by the rules of Civil Procedure of this court and not by the Iowa law. While the court has some discretion as to whether such an order should be made, it is quite generally held by the courts that such information is only to be furnished under such an order where the party cannot obtain the information by discovery as provided in the Rules of Civil

Procedure. Such information can be so obtained and the attorney for the Government advises that upon written application by letter or otherwise to him he will be glad to furnish a detailed statement of the analysis furnished to his office by the Government, but he does not care to be bound by that analysis as conclusive in the event he is able to show other filthy substance in the article sought to be condemned.

As the claimant can obtain the information requested, insofar as the same is in the possession of the attorneys for the Government, by the procedure authorized under Rule 33 of the Rules of Civil Procedure, and other rules of discovery, the motion for more specific statement should be overruled. The Clerk will therefore enter the following order:



[*Motion Overruled*]

The above entitled action having come on for hearing in open court at Des Moines, Iowa, on the 21st day of November, 1942, upon a motion by the intervening claimant for more specific statement, and the court being advised, said motion is overruled and the intervening claimant, Fred Jegerlehmer, excepts.

[On April 6, 1943, the claimant having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond with provision that it should not be sold or otherwise disposed of for human food, but that it could be used for animal food in compliance with the law.]

## UNITED STATES v. 62 PACKAGES, MORE OR LESS, OF MARMOLA PRESCRIPTION TABLETS

United States District Court for the Western District of Wisconsin. No. 139  
 Admiralty. February 23, 1943. 48 F. Supp. 878.

Affirmed, 142 F. 2d 107. See page 107.

Certiorari denied, *Raladam Co. v. United States*, 323 U. S. 731 (1944).

The Act was designed to regulate commerce in foods, drugs, and cosmetics, and to protect the public against foods, drugs, and cosmetics that are dangerous to health as well as those which are falsely branded.

Title, Federal Food, Drug, and Cosmetic Act.

It is well settled that Congress has the power, under the Commerce Clause of the Constitution, to condemn the interstate transportation of misbranded drugs and to make such articles contraband when so transported.

Sections 304 (a), 901, Federal Food, Drug, and Cosmetic Act.

The Fourth Amendment to the Constitution does not apply to seizure process in civil actions. A seizure proceeding is a civil, as distinguished from a criminal action. It is a proceeding *in rem* and need not be supported by an affidavit of probable cause.

Sections 304 (b), 901, Federal Food, Drug, and Cosmetic Act.

The seizure and misbranding sections of the Act do not provide for unreasonable searches and seizures.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

The words "dangerous to health," in Section 502 (j), provide a question of fact for determination by the court or jury and leave nothing for speculation.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

Section 201 (n) defines the scope of Section 502 (a). There is nothing indefinite or ambiguous in the sections.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The word "may" is used in Section 201 (n) in its ordinary sense and signification. By the section, the Government is restricted in its proof to material facts with respect to the consequences that may follow from the use of the article; hence there is no deprivation of property without due process of law.

Sections 201 (n), 901, Federal Food, Drug, and Cosmetic Act.

In the Act there is no unlawful delegation of legislative power by Congress, nor do the acts of the Government under the statute constitute an exercise of legislative power in violation of the Constitution.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.



*U. S. v. 62 Packages Marmola Prescription Tablets*

Congress may vest discretion in executive officers of the Government to promulgate regulations interpreting the statute, even to the extent of providing for penalizing one for a breach of such regulations.

Section 701 (a), Federal Food, Drug, and Cosmetic Act.

The statute, and the sections involved in the suit, were held to be well within the power of Congress to enact and not to violate any part of the Constitution.

Sections 201 (b), 201 (g), 201 (n), 304 (a), 502 (a), 502 (j), Federal Food, Drug, and Cosmetic Act.

Any drug, which for safety in its use requires diagnosis and evaluation, and which when taken as recommended in its label may expose the users to disease and pain, is dangerous to health.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

"Marmola," the drug proceeded against, contained  $\frac{1}{2}$  grain of dessicated thyroid in each tablet, and its label recommended a dosage of four a day. It was held dangerous to health since in it there was an inherent and potential danger that might reasonably be expected to attend its use when one considered that it would be used by the strong, the weak, the old, the young, the well, and the sick, without first having a physical examination or diagnosis of their condition by a competent physician.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous, who, when making a purchase, do not stop to analyze.

Title, Federal Food, Drug, and Cosmetic Act.

The Act was not intended to prevent self-medication. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user.

Sections 502 (a), 502 (j), Federal Food, Drug, and Cosmetic Act.

The Act should receive a liberal construction.

Title, Federal Food, Drug, and Cosmetic Act.

Marmola, when used as prescribed in its labeling, was dangerous to health, and its labeling was false and misleading in its representation that it was a safe remedy for obesity and in that it failed to reveal facts material with respect to consequences which might result from its use as prescribed in its labeling.

Sections 201 (n), 502 (a), 502 (j), Federal Food, Drug, and Cosmetic Act.

John J. Boyle, U. S. Attorney, Alvin M. Loverud, Assistant U. S. Attorney; both of Madison, Wis.; Daniel P. Willis, Senior Attorney, Federal Security Agency, Washington, D. C., for plaintiff.

William H. Dougherty, Paul N. Grubb, Stanley M. Ryan, all of Janesville, Wis.; Rockwell T. Gust and David A. Howell of Detroit, Mich., for defendant.

### Memorandum Opinion

#### [*Libel for Condemnation*]

PATRICK T. STONE, District Judge: This is a libel for condemnation, under the provisions of the Federal Food, Drug, & Cosmetic Act of June 25, 1938, (c. 675, 52 Stat.

1040; Title 21, U. S. C. A., § 301 et seq.) of 62 packages of Marmola Prescription Tablets which had been transported in interstate commerce from Detroit, Michigan, to La Crosse, Wisconsin, by the intervener the Raladam Company. The libel charges that the Marmola Tablets under seizure



were misbranded within the meaning of Section 502 (j) of said Act (21 U. S. C. A. 352 (j)) in that the article is dangerous to health when used in the dosage or with the frequency prescribed, recommended or suggested in the labeling thereof, and within the meaning of Sections 502 (a) and 201 (n) of said Act (21 U. S. C. A. 352 (a) and 321 (n)) in that the labeling is false and misleading because it fails to reveal facts material with respect to consequences which may result from the use of the article under the conditions of use prescribed therein.

[*Contentions of Claimant*]

The Raladam Company intervened in this action as claimant of the seized article, and answered denying the allegations in the libel, and alleged that Sections 201 (n) and 502 (a) of said Act (21 U. S. C. A. 321 (n) and 352 (a)), were not in force at the time of the alleged violation; that the Federal Food, Drug, and Cosmetic Act and each section thereof relied upon by the Government in these proceedings, is unconstitutional for the reasons (a) it provides for unlawful search and seizure; (b) it is too indefinite and uncertain in its provisions; and (c) that said sections contemplate or constitute an unlawful delegation of legislative powers, all in violation of Articles I, II and III of the Constitution of the United States.

[*Facts Stipulated*]

The parties stipulated that the tablets seized had been transferred in interstate commerce; that the Marmola Prescription Tablets contained the following ingredients:

1 grain	Extract Bladderwrack
½ grain	Extract Phytolacca
¼ grain	Extract Cascara Sagrada
	Rx. 87 Spec.
½ grain	Desiccated Thyroid
16/1000 min.	Oleoresin Ginger
	Po. Saccharum special
3 grains	Calcium Carbonate
	Precipitated
1/24 min.	Methyl Salicylate
1/24 min.	Oil Anise
1/24 min.	Oil Sassafras
	Talc Brown
	Ivory Black
	Aqua for Extracts
	Po. Burnt Umber

Red Oxide of Iron  
 Syrupus Simplex  
 Lubricating Solution  
 Aqua for Granulating  
 Liquid Petroleum Colorless

They further stipulated as follows:

"4. These tablets were manufactured for the Raladam Company by the Arner Company, Inc., from ingredients furnished by Parke, Davis & Company and Parke, Davis & Company has either supplied the active ingredients for or actually manufactured Marmola Prescription Tablets for more than twenty (20) years preceding the commencement of these proceedings, during which period over Twenty Million (20,000,000) packages have been sold by the Raladam Company.

"5. During the past twenty (20) years no change has been made in the ingredients or in the amounts thereof used in Marmola Prescription Tablets except that during the last World War when Cascara Sagrada was temporarily unavailable ¼ grain phenolphthalein was temporarily substituted for the ¼ grain of Cascara Sagrada in the Marmola formula.

"6. The ½ grain of Desiccated Thyroid contained in each Marmola Prescription Tablet is and was at all times during the last twenty (20) years a product of Parke, Davis & Company, and during all of said time all Desiccated Thyroid manufactured and sold by Parke, Davis & Company, which amounts to many millions of grains annually, has contained approximately fifty per cent (50%) more Organic Iodine than the mean average for Desiccated Thyroid as specified in the United States Pharmacopoeia.

"7. The only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of Desiccated Thyroid contained in each tablet."

[*Statutory Provisions Involved*]

The following provisions of the Federal Food, Drug, and Cosmetic Act are involved in these proceedings:

Section 201, 32 Stat. 1040 (21 U. S. C. A. 321):

"(g) The term 'drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for



*U. S. v. 62 Packages Marmola Prescription Tablets*

use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories."

"(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the intent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use as are customary or usual."

Section 304 of the Act (21 U. S. C. A. 334), which pertains to the method of seizure and disposition of misbranded food and drugs moving in interstate commerce; and Section 502 (21 U. S. C. A. 352) which reads in part as follows:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular.

"(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

Section 902 of the Act provides for the effective date of the Act, and reads in part:

"\* \* \* That sections 502 (j), 505 and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act \* \* \*" which was June 25, 1938.

Section 201 (b) (21 U. S. C. A. 321 (b)) defines interstate commerce as follows:

"The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof \* \* \*."

[Labeling Involved]

The labeling involved consists of the printed matter found on the box containing the Marmola Prescription Tablets and in the booklet accompanying same. The portions that are material to the disposition of the issues herein are as follows:

(On Box)

"DIRECTIONS

"Take one tablet before each meal and at bedtime with enough water to swallow

easily or as directed by a physician. Marmola is recommended *only* as a treatment for adult fat persons whose excess fatness is caused by hypothyroidism with accompanying subnormal metabolic rates but who are otherwise normal and healthy. Marmola should not be taken by persons suffering from any abnormal condition except abnormal excess fat caused as above stated. We make no diagnosis as that is the function of your physician who must be consulted for that purpose. Marmola is not recommended for children. *Before taking be sure to read enclosed circular.*"

(In Booklet)

"THE PURPOSE OF MARMOLA

"Marmola prescription tablets have been sold to the public for more than thirty years and more than twenty million boxes have been distributed during that period. Marmola is not sold as a cure-all. It is intended for use only by obese (Obesity is the term used by the medical profession for an excessive development of fat throughout the body) persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism, and our statements and representations made herein or otherwise are strictly limited to this treatment under these conditions and according to the dosage as recommended. We do not make any diagnosis as that is the function of your physician, who must be consulted for that purpose. Marmola should not be taken by persons suffering from any abnormal condition except obesity (abnormal excess fat) caused as above stated. The complete formula will be found on page 25. Purchasers who decide or are advised they do not need Marmola may obtain refund of the purchase price of any unused package by returning it to the Raladam Company at Detroit.

"IMPORTANT DIRECTIONS

"First

"Take one Marmola tablet before each meal and one at bedtime—four a day. Do this regularly.

"Second

"For best results we recommend that Marmola be used as directed over a period of sixty to ninety days—if needed that long.

"Marmola is intended to be used as a week-by-week treatment. The dosage is not intended to cause rapid reduction of weight. Most authorities advise a moderate rate of reduction so the body and skin may adapt themselves to the changed conditions.



"The rate of reduction differs with individuals. Habits also affect it. To some results appear rapid, to others slow. No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unpleasant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. Such a condition can not always be predicted either by physicians or others. If any unpleasant effects are experienced stop taking *Marmola* until they disappear, then resume taking one-half of the former dosage or consult a physician.

#### "How Quick?

"Fat reduction under the *Marmola* treatment does not usually start at once. It may take a few days—even up to two weeks—to get things started in the right direction. But the start, when it comes, means much, and it sometimes comes with a spurt. The chief purpose of *Marmola* is to aid in the correction of a deficiency in those obese persons who are otherwise normal and healthy and in whom the lack of the substance supplied by *Marmola* causes the accumulation of excess abnormal fat. The first dose of *Marmola* starts a new supply of this factor, but slowly, so it takes a little time to become apparent. Do not be impatient.

#### "Diet and Exercise

"The makers of *Marmola* do not advise abnormal exercise or diet. Extreme measures should not be undertaken. Abnormal exercise in an obese condition may overtax the heart. Starvation diets may lead to a deficiency in vitamins and minerals.

"But there is no question that reasonable habits in these respects greatly aid results. Do not throw too great a burden on *Marmola*.

"Normal activity, like walking, is suggested but not anything too strenuous without an examination. Moderation in the use of fat-forming foods will aid what you are seeking. But exercise and diet alone cannot be relied upon where there is a deficiency which causes too much food to go to fat. *Marmola* supplies a factor needed in the correction of this deficiency, where the lack of the substance it supplies has caused the accumulation of the abnormal excess fat.

#### "Suggestions

"Avoid starches and sweets in excess. Starchy foods include bread and potatoes. Cut down fatty foods. Instead of them,

eat poultry, eggs, lean meat, clear soups, fish and sea foods. All kinds of fruits and fresh vegetables are good for you. Eat all you want of them. But be sparing the foods with high calory content, like sugar, cereals, and fat. We do not recommend any great self-denial, but simply a reduction of work which *Marmola* is intended to do.

"Moderate exercise helps to keep you healthy. Walking is a good exercise. Deep breathing in the open air is good for you, for it supplies oxygen to the blood. Chew all foods well. At every meal eat a little less than you think you need. These things are suggested to hasten the results you seek, by giving *Marmola* something less to do.

"In the 30 years of *Marmola*, it is quite natural that many people who have heard about it, but not used it, may have developed wrong ideas. That is why the complete formula is published in this little book.

"The idea that excess fat is always due solely to laziness or gluttony has been dissipated by science. One may be active and eat moderately and still grow fat, if a deficiency exists which causes too much food to be converted into fat instead of energy.

"*Marmola* is a time-tested aid to correct this basic cause of the abnormal excessive fat accumulated by reason of the deficiency it is designed to correct. There is no claim to quick and amazing results. A mere hot bath might bring greater quick results by simply draining so much water from the system. But such loss in weight is temporary and unimportant. *Marmola* aims at the basic cause and supplies a deficiency and thus brings real results whenever this deficiency exists. The *Marmola* prescription is compounded by a famous medical laboratory and every ingredient and every percentage has been tested by years of experience.  
\* \* \*

#### "When to Stop

"Stop *Marmola* when your weight comes down to normal. A table in this booklet tells you the average weight of persons of your height and age. Your ideal weight may be either more or less than the average. But you are the best judge of the weight at which you feel the best and are most efficient. Stop taking *Marmola* as soon as you lose your abnormal excess weight. If, later, you should start to gain again take more *Marmola* tablets until conditions are corrected.

"The time required differs with conditions. The use of *Marmola* by those who need it normally results in greater en-



*U. S. v. 62 Packages Marmola Prescription Tablets*

ergy and vitality. Our medical advisers do not recommend the taking of *Marmola* as a tonic after the excess fat is gone. This might lead to becoming too thin. Nor should it be taken if any condition arises which inhibits its use. Consult your physician if any unusual circumstances or conditions arise.

"\* \* \* Consult your physician if you want special advice in any unusual condition. We do not make any diagnosis, as that requires personal contact. If you want advice in any special condition or desire more advice than we give you in this book, get it from a physician. We do not prescribe in special cases by letter.

"Your doctor, of course, is opposed to self-medication. He may prefer to write his own prescription for some special case, but the *Marmola* prescription has been developed by over 30 years of experience and its efficiency has been tested by the sale of over 20,000,000 boxes throughout the world."

*[Trial and Witnesses]*

This case was ably tried by counsel for both parties. Testimony of experts, specialists and investigators, highly qualified in their particular branches of medicine, was submitted by both parties. Voluminous evidence was presented, which included testimony relating to internal medicine, nutrition, chemistry, obesity, endocrinology, thyroid diseases, metabolism, tuberculosis, diabetes, heart diseases, nervous disorders, and many other diseases of the human body. The Government's witnesses included eminent specialists in endocrinology, obesity and thyroid diseases, among whom were Dr. James Short of New York City, a specialist in internal medicine; Dr. Frank Stites of Louisville, Kentucky, a specialist in internal medicine; Dr. Elmer L. Sevringhaus of Madison, Wisconsin, a professor in the medical school of the University of Wisconsin and a specialist in metabolic and endocrine diseases; Dr. Willard O. Thompson, Chicago, professor in the medical school of the University of Chicago and a specialist in endocrinology and metabolism; Dr. Louis H. Newburgh of Ann Arbor, Michigan, a professor in the medical school of Michigan University and a specialist in endocrinology and metabolic diseases; Dr. Isral Bran of Philadelphia, Pennsylvania, a specialist in thyroid diseases. Two members of the staff of Mayo Clinic, Rochester, Minnesota, testified on behalf of the Government. One, Dr. Russell M. Wilder, an instructor in the medical school of the Uni-

versity of Minnesota, is a specialist in the treatment of diabetes; the other, Dr. Samuel F. Haines, is the head of the section of the clinic pertaining to thyroid diseases, and is also an associate professor at the University of Minnesota.

Other Government witnesses were Dr. William Oatway, Madison, Wisconsin, member of the faculty of the medical school of the University of Wisconsin, and on the staff of the Wisconsin General Hospital in charge of the thoracic services, including tuberculosis; Dr. Chester M. Kurtz of Milwaukee, Wisconsin, also a member of the faculty of the medical school of the University of Wisconsin, and a specialist in heart diseases; Dr. Anton J. Carlson, Chicago, eminent physiologist who had a professorship in the department of physiology at Rush Medical College and the University of Chicago from 1904 until recently when he retired; and Dr. Marian S. Kimble of Madison, a chemist who, as an investigator, made tests as to the value of desiccated thyroid as a remedy for obesity.

Among those testifying for the intervenor were Dr. Abbott W. Allen of New York, assistant clinical professor of medicine of Columbia University; Dr. John A. Killian of Englewood, New Jersey, a biochemist, former instructor of physiology and physiological chemistry at the medical school of Fordham University, and now professor of biochemistry at the New York Post-Graduate School of Columbia University; Dr. Plinn T. Morse of Detroit, Michigan, former instructor in pathology of the University of Michigan and the Detroit College of Medicine, and at present consulting pathologist in Detroit; Dr. William A. Spitzley of Detroit, a general practitioner of wide experience; Dr. Benjamin H. Schlomovitz of Milwaukee, Wisconsin, professor of pharmacology and toxicology at Marquette University Medical School, and a consulting pathologist; and Dr. Andrew I. Rosenberger of Milwaukee, Wisconsin, a specialist in diseases of the nervous system.

*[Questions Before the Court]*

The principal questions before the Court are:

First: Is the Federal Food, Drug, and Cosmetic Act unconstitutional?

Second: Is the *Marmola* tablet dangerous to health when used in the dosage or with the frequency and duration prescribed, recommended or suggested in the labeling thereof?



Third: Is the Marmola labeling false and misleading in the representation that Marmola is a safe remedy for obesity?

Fourth: Does the labeling reveal facts material with respect to consequences which may result from the use of Marmola under the conditions of use prescribed in the labeling?

[*Grounds Urged for Unconstitutionality*]

Intervener asserts that the act, and particularly the sections thereof under which these proceedings are brought, are unconstitutional and void because (1) they permit an unlawful search and seizure in violation of the Fourth Amendment to the Constitution of the United States; (2) that the statute and the said sections thereof violate the Fifth Amendment to the Constitution in that they are too indefinite and uncertain to apprise intervener of the offenses attempted to be defined therein; (3) that the statute constitutes an unlawful delegation of legislative powers in violation of Articles I, II, and III of the Constitution of the United States.

[*Unreasonable Search and Seizure*]

The statute, like its predecessor, was designed to regulate commerce in food, drugs and cosmetics, and to protect the public against foods and drugs that are dangerous to health, as well as those that are falsely branded. It permits the administrative agencies of the Government, charged with its enforcement, to continue to function as under the former act. It is well settled that Congress has the power, under the commerce clause of the Federal Constitution, to condemn the interstate transportation of misbranded drugs, and to make such articles contraband when so transported. *McDermot v. Wisconsin*, 228 U. S. 115; *Hipolite Egg Co. v. U. S.*, 220 U. S. 45.

The Fourth Amendment to the United States Constitution does not apply to a seizure process in civil actions. The sections of the act here in question do not provide for unreasonable searches and seizure. This is a civil action as distinguished from a criminal action. It is a proceeding *in rem* and need not be supported by an affidavit of probable cause. *U. S. v. Geo. Spraul & Co.*, 185 Fed. 405; *U. S. v. Two Barrels of Desiccated Eggs*, 185 Fed. 303.

[*Indefiniteness*]

Section 502 (j) (21 U. S. C. A. 352 (j)) declares a drug to be misbranded if it is

dangerous to health when used in the dosage or with the frequency prescribed in the labeling thereof. The words "dangerous to health" provide a question of fact for determination by the Court or jury and leave nothing for speculation.

Section 502 (a) (21 U. S. C. A. 352 (a)) declares a drug to be misbranded if its labeling is false or misleading in any particular. Section 201 (n) (21 U. S. C. A. 321 (n)) defines the scope of Section 502 (a). There is nothing indefinite or ambiguous in Sections 201 (n) or 502 (a).

Proofs under the statute are limited to material facts omitted from the labeling with respect to consequences that may result from the use of the article. The word "may" is here used in its ordinary sense and signification, there being nothing to show the intention of Congress to affix any other meaning to it. By Section 201 (n) the Government is restricted in its proof to material facts with respect to the consequences that may follow the use of the article; hence there can be no deprivation of intervener's property without due process of law.

[*Delegation of Legislative Power*]

In the act there is no unlawful delegation of legislative power by Congress, nor do the acts of the Government pursuant to the provisions of the statute constitute an exercise of legislative power in violation of the Constitution. Congress may vest discretion in executive officers of the Government to promulgate regulations interpreting the statute even to the extent of providing for penalizing one for a breach of such regulations. *U. S. v. Grimaud*, 220 U. S. 506; *Union Bridge Co. v. U. S.*, 204 U. S. 364; *Hampton & Co. v. U. S.*, 276 U. S. 394.

In the statute Congress has set up its own policies and standards. There is no delegation of legislative powers to executive officers of the Government. No executive regulations with the force and effect of law are here involved. The statute and the sections thereof involved in these proceedings are well within the powers of Congress to enact and do not violate any part of the United States Constitution or its amendments.

[*Composition of Marmola Tablets*]

The Marmola tablets which are offered to the public as a treatment for obesity contain a number of ingredients, but the only one involved in this action is the  $\frac{1}{2}$  grain of



desiccated thyroid contained in each tablet, and which contains 0.3% organic iodine, which is about 50% more organic iodine than is contained in desiccated thyroid prepared according to the standards of the U. S. Pharmacopoeia. One-third to one-half of the organic iodine in desiccated thyroid consists of thyroxin, which is the active principle of the thyroid hormone secreted by the thyroid gland. The potency of desiccated thyroid is proportional to its organic iodine content, consequently the Marmola tablet produces a greater physiological effect than the same amount of desiccated thyroid prepared according to the standards of the United States Pharmacopoeia.

*[Representations and Dosage Recommended]*

The labeling represents that Marmola is intended as a cure for obesity and is for use only by obese persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism; that hypothyroidism is the basic cause of obesity which results from a lack of a substance which Marmola supplies. The daily dosage recommended is equivalent to two grains of desiccated thyroid containing 0.3% organic iodine, or to three grains of desiccated thyroid containing 0.2% organic iodine, prepared according to the standard of the United States Pharmacopoeia.

*[Causes of Obesity]*

Obesity is defined as an excessive development or excessive storage of fat throughout the body. There is a difference of opinion among the experts who testified as to the cause of obesity and its remedy. Some of the Government witnesses testified that overweight is caused by excessive eating and lack of proper exercise; that the weight may be reduced by dietary measures coupled with adequate exercise. Some of claimant's witnesses testified that a large proportion of cases of obesity are caused by endocrine disturbances or disorders; that the thyroid gland is the regulator of the metabolic processes and that obesity is due at least in a large part to a deficient activity in this gland, and hence in its treatment thyroid medication is necessary. Other witnesses were of the opinion that obesity is caused both by overeating and by endocrine disturbance.

*[Hypothyroidism]*

Hypothyroidism is a word which denotes the underfunctioning of the thyroid gland,

which is a condition of disease. It is accompanied by a subnormal basal metabolic rate and by other symptoms, such as dryness of skin, scarcity of hair and eyebrows, sluggishness of physical and mental reactions, decreased appetite, slower pulse rate and characteristic changes in the composition of the blood, and, in advanced stages of hypothyroidism or myxedema, by puffy and swollen appearance of the face and other parts of the body due to a collection of mucoid fluid beneath the skin.

*[Metabolism]*

By metabolism is meant the total of the various processes by which food is transformed in the body into the chemicals which are absorbed into the blood stream and lymphatic system for the purpose of nourishing the body so that it can carry on its work. The health of the body depends upon the well-balanced use of the body chemicals. Metabolism denotes all the processes of the body by which food is used, body heat and energy created, and the body built up or repaired, and by which the tissues of the body are destroyed and waste matter excreted.

The rate of metabolism is measured by the rate at which the body produces or gives off heat. The "Basal metabolic rate" is defined as the least rate of chemical activity which will maintain the absolutely essential functions of the body sufficiently to keep an individual alive. Every activity of the body increases the amount of energy consumed. Having found the basal requirements of an individual, the physician can, by the addition of the demands of the individual's other activities, compute what his total needs will be. Average normal standard rates have been established by tests, and the results are expressed in terms of either plus or minus variations from the standard. In the same classification normal healthy people vary one from another in the normal basal metabolic rate. The great majority vary only to the extent of 10% more or 10 % less in the amount of heat produced, represented by the average normal standard. Normal healthy people may vary from the average standard normal rate to even a greater extent, but seldom more than 15% more or less than standard, which means that the individual is consuming 15% more or 15% less energy than the average among normal people.



*[Desiccated Thyroid for Treatment of Hypothyroidism]*

Desiccated thyroid is used in the treatment of hypothyroidism, and the optimum dosage in such treatment must be determined for each individual case. It varies with each individual and is established only by trial and error. The optimum daily dosage may be as little as  $\frac{1}{4}$  grain per day, and in most cases less than 2 grains per day, although there are some cases that exceed 2 grains per day, depending upon the underfunctioning of the individual's thyroid gland.

*[Effect of Overdosage of Desiccated Thyroid]*

There was a substantial agreement among the medical witnesses that the overdosage of desiccated thyroid results in an increase in the metabolism of the patient; that it has a toxic effect on people that are hypothyroid in that it increases their basal metabolic rate and injuriously affects the functioning of the endocrine glands, kidney and liver, impairing their capacity for normal functioning; that it places an extra burden on the organs of the body; that it results in symptoms which cannot be distinguished from those disclosed in spontaneous hyperthyroidism, such as rapid heart, heart pains, shortness of breath, sleeplessness, nervous and emotional instability, headaches, dizziness, tremor, muscular weakness, disturbances of the alimentary canal, fatigue, nausea, and, in women, menstrual disturbances; that the symptoms of hyperthyroidism will disappear days or weeks after the discontinuance of desiccated thyroid, but it sometimes results in the precipitation of a more serious and permanent disease and injury to health; that many people who consider themselves normal and healthy, and who are completely unaware that they are suffering from any hidden disease, have been found to have physical impairments or diseases in a mild or incipient form such as impairment of the heart, diabetes, or tuberculosis, which may be discovered only by a thorough examination by an experienced physician; that in such cases a dosage of two grains of desiccated thyroid a day aggravates the disease or ailment or accelerates the onset of their more serious phases. This fact was established by the testimony of experts and investigators learned in endocrinology and familiar with the physiological manifestations of thyroid, based on their study, experience, and clinical observations. Dr. Short testified that many people have heart ailment and are

completely unaware of it; that he made a study of 2400 male persons who were supposedly healthy, which he placed in three groups. The first group included those who had normal hearts according to the electrocardiogram. There were 811 in this group. Group 2 included 1330 persons who had borderline impairments that might or might not be significant of heart disease. Group 3 included 250 persons who had a very definite impairment of the heart. In group 2, 90% had no symptoms and were unaware of any possible heart ailment. In group 3, those having definite impairment, 87% had no symptoms and were unaware of heart injury.

Dr. Russel M. Wilder testified that many people have diabetes and are unaware of it; that the records of the Mayo Clinic for the year just preceding the date of his appearance as a witness herein, showed that of approximately 100,000 patients received at the Clinic, about 1700 were suffering from diabetes; that about  $\frac{1}{5}$  of the 1700 came to the Clinic without any knowledge that they had this disease; that desiccated thyroid is definitely harmful to a diabetic; that when a person develops hyperthyroidism, his diabetes is invariably aggravated.

Dr. Oatway testified that many people have tuberculosis and are unaware of it; that from his investigations and tests he discovered that  $\frac{9}{10}$  of those suffering from active tuberculosis were unaware of it.

The medical testimony was substantially all to the effect that in sound medical practice a doctor will prescribe thyroid for hypothyroidism only after a careful physical examination is made of the patient's head, eyes, throat, chest, lungs, heart, abdomen, and reflexes covering the nervous system of the patient to ascertain if the patient is suffering from any latent or underlying disease of which he is unaware, such as diabetes, tuberculosis, or heart ailment. In some instances a basal metabolism is done, X-rays of the chest are made and an electrocardiogram of the heart is obtained.

*[Inherent and Potential Danger of Marmola]*

Any drug, which for safety in its use requires diagnosis and evaluation, and when taken in the dosage and with the frequency recommended and suggested in its labeling, may expose the users to disease and pain, is dangerous to health. Marmola is such a drug. In it there is an inherent and potential danger that may reasonably be expected to attend its use when one considers that it will be used by the strong, the weak, the



*U. S. v. 62 Packages Marmola Prescription Tablets*

old, the young, the well, and the sick, without first having a physical examination or a diagnosis of their condition by a competent physician.

Obesity is not caused by hypothyroidism. Those suffering from hypothyroidism are sometimes over-weight due to the deposit in the body of a mucoid substance which is not fat and which desiccated thyroid may remove under proper treatment. Desiccated thyroid may stimulate the appetite and its use may result in increased weight unless the dosage is so large as to result in hyperthyroidism, which is a disease.

Obesity is not affected materially by the use of Marmola prescription tablets as prescribed or by desiccated thyroid of comparable daily dosages, except by producing and maintaining a condition of hyperthyroidism. The discontinuance of Marmola on the appearance of unpleasant effects or unusual circumstances or conditions does not avoid danger. When these effects or conditions appear, the user is in a state of hyperthyroidism, which, in some cases, may result in the precipitation of more serious and permanent injury.

*[Conclusions Public Would Receive from Marmola Labeling]*

The substantial portion of the public, after reading the labeling in question, would conclude that obesity is caused by the lack of some substance in the human body that Marmola supplies; that Marmola is a safe and efficient remedy for obesity, which is not a fact. The labeling fails to inform the prospective user that if he is suffering from hypothyroidism, he is not healthy and normal. It places a duty upon the user to make a self-diagnosis to determine if he is suffering from hypothyroidism. The layman lacks familiarity with medical terminology. He has little or no knowledge of medical science, and does not possess that skill and learning required to determine whether he is suffering from hypothyroidism. The labeling does not recommend that an obese person considering the use of Marmola should first consult a physician. It does advise that he consult a physician if he desires special advice in any unusual conditions or more advice than appears on the label. It suggests that the doctor is opposed to self-medication and might

prefer to write his own prescription.

*[Federal Act Should Receive Liberal Construction]*

The Federal Food, Drug, and Cosmetic Act was not made for experts, nor is it intended to prevent self-medication. The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user. It should receive a liberal construction. *U. S. v. Lee*, 131 F. (2d) 464; *Florence Mfg. Co. v. Dowd Mfg. Co.*, 178 F. 73; *Aronberg v. Federal Trade Commission*, 132 F. (2d) 165.

*[Marmola Dosages Should Be Under Supervision of Doctor]*

The administration of thyroid tablets in Marmola dosage is a dangerous procedure, and should not be undertaken without a thorough examination of the prospective user by a competent physician, and then only under the supervision of the doctor.

*[Marmola Held Dangerous and Misbranded]*

The Court is thoroughly convinced, by a preponderance of the evidence, that Marmola, when used as prescribed in the labeling thereof, is neither a safe, appropriate, nor an efficient remedy for obesity; that it is dangerous to the health of the user when used in the dosage or with the frequency and duration prescribed, recommended or suggested in the labeling thereof; that the packages of Marmola in question, when seized in these proceedings, were misbranded within the meaning of the sections of the Federal Food, Drug and Cosmetic Act involved herein; that the labeling on Marmola is false and misleading in its representations that it is a safe remedy for obesity, and in that it fails to reveal facts material with respect to consequences which may result from the use of Marmola under the conditions prescribed in the labeling.

*[Act in Force at Commencement of Proceedings]*

The contention of the intervener that the sections of the act involved in these proceedings were not in force at the time of



the seizure of the Marmola packages is disposed of by Section 902. It is clear from the reading of that statute that these sections were in force at the time of the commencement of these proceedings.

[Decree of Condemnation]

The libelant is entitled to a decree of condemnation as prayed for in the libel, with costs, and other proper expenses to be taxed against the intervener.

UNITED STATES v. 935 CASES, MORE OR LESS, EACH  
CONTAINING 6 No. 10 CANS OF TOMATO PUREE,  
LADOGA CANNING COMPANY

United States Circuit Court of Appeals, Sixth Circuit. No. 9514. Decided June 22, 1943. Filed June 28, 1943. 136 F. 2d 523.  
Certiorari denied, *Ladoga Canning Company v. United States*,  
320 U. S. 778 (1943).

Recognition that seizure proceedings under the predecessor Food and Drugs Act of 1906 should conform to proceedings in admiralty was given by the Supreme Court in *Four Hundred and Forty Three Cans of Frozen Egg Product v. United States*, 226 U. S. 172. It was commented there that it was not intended to liken the proceedings to those in admiralty beyond seizure of the property by process *in rem*.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

Under the seizure action of the Act, the United States is authorized to seize adulterated or misbranded articles of food before proof of justification for seizure.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Admiralty Rule 21 controls the libel procedure under the Act.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

Under the Act, a libel *in rem* needs no verification.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

A seizure proceeding under the Act is not, in any aspect, a criminal case. An ordinary libel *in rem* brought by the United States is undoubtedly a civil action.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Under the Interstate Commerce Clause of the Constitution, Congress has been vested with full power to keep the channels of interstate commerce free from the transportation of illicit or harmful articles, and to make those deleterious to public health "outlaws of such commerce." So long as the means are appropriate to that end and do not violate any provision of the Constitution, Congress may be the judge of the means to be employed in exercising its powers.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The use of the words "warrants of arrest" in the Admiralty Rules bears no semblance to the use of the word "warrant" in the Fourth Amendment. In admiralty, the term "arrest" is the technical term long sanctioned to indicate an actual seizure of property.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

A libel *in rem* under the Act is not a search and seizure within the meaning of the Fourth Amendment, and the libel of information need not be verified.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.



*U. S. v. 935 Cases Tomato Puree*

F. B. Kavanagh (Don C. Miller with him on brief), Cleveland, Ohio, for appellant.

Edwin H. Chaney of Squire, Sanders & Dempsey, Cleveland, Ohio (W. C. Bachelder of Bachelder & Bachelder, Indianapolis, Ind., with him on brief), for appellee.

Before HAMILTON, MARTIN and McALLISTER, Circuit Judges.

[Charge]

MARTIN, Circuit Judge: The United States Attorney for the Northern District of Ohio filed, in behalf of the United States, a libel *in rem* against a quantity of tomato puree shipped by appellee, Ladoga Canning Company in interstate commerce from Lebanon, Indiana, to Cleveland, Ohio. The complaint charged that, under the Federal Food, Drug, and Cosmetic Act, the food was subject to seizure and confiscation pursuant to U. S. C. A., Title 21, Section 334, as adulterated food within the meaning of U. S. C. A., Title 21, Section 342 (a) (3).

[Proceedings Below]

The appellee, averring its sole ownership of the goods, appeared specially and moved to quash the writ of attachment and monition and the attachment and seizure of the goods; and, in the same motion, prayed for an order for the return of the goods to appellee upon the allegation that the issuance of the writ and the seizure of the goods violated the Fourth Amendment to the Constitution of the United States, "in that the warrant for the seizure issued and in that the seizure was made without a showing of probable cause supported by oath or affirmation, particularly describing the place to be searched and the things to be seized."

The District Court entered an order sustaining the motion, directing that the goods be returned to the owner, and dismissing the complaint. On the following day, the United States Attorney filed notice of appeal to this court. Six days later, the District Court entered an order directing that, pending the perfection of the appeal, "the operation and enforcement of the judgment entered be, and the same is ordered stayed, insofar as the return of the goods is concerned." After another six-day interim, the appellee moved for a modification of the latter order by striking therefrom the provision concerning the stay of the return of its goods. The point was made that the order of the Court quashing the warrant and directing the return of the goods to the owner is "a separate matter," is an interlocutory order and, therefore, not appealable (See *Wise v. Mills*, 220 U. S. 546). The

motion stated further that "the continued holding of the goods is subject to the same objection as the original seizure; namely, that it is contrary to the constitutional provisions against unwarranted searches and seizures." On March 30, 1943, the District Court entered an order denying the motion of appellee for modification of the Court's order "staying proceedings."

[Motion for Dissolution of Order]

On April 13, 1943, while the record in the cause was being printed, appellee filed in this court a motion, with an accompanying brief, for dissolution of the order of March 17, 1943, filed in the District Court, insofar as that order "stays the enforcement of the part of the order of March 10, 1943, which directed that the goods theretofore seized by the Marshal in violation of the Fourth Amendment of the Constitution of the United States be released from seizure and delivered to appellee."

The printed record was subsequently filed on April 23, 1943, and hearing of the motion ensued on June 1, 1943. Upon this hearing, the attorneys for the parties argued the case upon the merits of the appeal, as well as upon the motion, and jointly besought this court not only to pass upon the motion to dissolve the District Court's stay order of March 17, 1943, but to decide the issue as to whether the District Court erred in dismissing the libel on information filed by the United States Attorney.

[Issue Whether Libel Must Be Verified]

The important issue for determination is whether a libel *in rem*, prosecuted in behalf of the United States pursuant to the Federal Food, Drug, and Cosmetic Act of June 15, 1938, Ch. 675, must be verified. The Act provides, *inter alia*:

"Any article of food, drug, device or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not under the provisions of Section 344 or 355, be introduced into interstate commerce shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any



district court of the United States within the jurisdiction of which the article is found. . . . [U. S. C. A., Title 21, Section 334 (a).]

"The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury." [U. S. C. A., Title 21, Sec. 334(b).]

[*Admiralty Proceedings*]

Recognition that proceedings under the provisions of Section 10 of the Pure Food Act of June 30, 1906, 34 Stat. 768, where this procedure was originally prescribed by Congress, shall be by libel *in rem* and shall conform as nearly as may be to proceedings in admiralty was given by the Supreme Court in *Four Hundred and Forty-Three Cans of Frozen Egg Product v. United States*, 226 U. S. 172, 178, 182, 183. It was commented there that the provision of the Act giving to either party the right to demand a jury trial of issues of fact was inserted with a view to removing any question as to the constitutionality of the Act, and that it was not intended to liken the proceedings to those in admiralty beyond *seizure of the property by process in rem*.

Under the quoted paragraphs of the Act of Congress, the United States is authorized to seize adulterated or misbranded articles of food before proof of justification for seizure; but adequate provision is made for a hearing before condemnation of the goods seized. In admiralty, procedure by libel *in rem* is akin to the civil writ of attachment, and the procedure followed in the instant case conformed to admiralty practice. Admiralty Rule 21 controls the libel procedure under the Federal Food, Drug, and Cosmetic Act. This rule does not specify that verification of the information or libel of information is required. Admiralty Rule 22, however, directs that all libels in *instance causes*, civil or maritime, shall be on oath or solemn affirmation. This difference in the two admiralty rules leads to the inference that the omission of the requirement of oath and affirmation to a libel filed under the Federal Food, Drug, and Cosmetic Act was deliberate.

The rules in admiralty effective in the United States District Court for the Northern District of Ohio expressly except the United States from the requirement of veri-

fication of pleadings. Admiralty Rule 1 of that district, which is the forum in the instant case, prescribes that "pleadings and answers to interrogatories, except on behalf of the United States, shall be verified." Similar local admiralty rules, excepting the United States from the requirement of verification placed on other libelants, have been adopted in the United States District Courts in many districts, among others the Western District of New York, the Eastern District of Pennsylvania, the Eastern District of South Carolina, the Southern District of Georgia, the Eastern District of Louisiana, the Western District of Kentucky, the Southern and the Northern Districts of California, the District Court of New Jersey, the District Court of Minnesota, the District Court of Hawaii, and the District Court of Puerto Rico. See *Benedict on Admiralty*, 6th Ed., Vol. 5. This authoritative textbook asserts that "all libels, except those brought on behalf of the Government, must be verified, even if also signed by the Proctor." *Benedict on Admiralty*, 6th Ed., Vol. 2, p. 71, Sec. 240. In a footnote, the author states that "the practice was laid down in *Hutson v. Jordan* (1837), 1 Ware (385) 393, 12 Fed. Cas. No. 6959 (D. Me.)."

[*Libel Needed No Verification*]

It is reasonable to assume that, in enacting the Federal Food, Drug, and Cosmetic Act for the protection of the public against consumption of impure, adulterated or misbranded articles, by setting up procedure for immediate removal of suspected articles from the flow of interstate commerce, the Congress, presumably familiar with admiralty rules and practice, considered public policy best conserved by not requiring United States Attorneys to verify libels filed in their official capacities against articles to be seized. All official acts of a United States Attorney are under his oath of office. This fact differentiates his status from that of other libelants. Though the question presented is of first impression in the appellate courts of the United States, we have reached, without hesitation, the conclusion that, under existing law, the libel *in rem* filed by the United States Attorney in the case at bar needed no verification.

[*Unreasonable Search or Seizure Charged*]

But the appellee contended successfully in the District Court that, irrespective of admiralty rules and practice, the issuance of



the writ of attachment and the seizure of the goods, without a showing of probable cause supported by oath or affirmation, were violative of the Fourth Amendment to the Constitution of the United States. The main dependance of appellee is *Boyd v. United States*, 116 U. S. 616, 622, in which the Government had seized goods charged to have been imported fraudulently in contravention of National revenue laws. The owners of the goods denied the fraud charged against them and the case was tried upon that issue. As part of its essential proof, the Government was compelled to show the value of the goods. In his effort to comply with this necessity, the United States Attorney, over objection of the owners, obtained a court order requiring them to produce the invoice covering the goods. Exception was taken by the owners to admission of the invoice in evidence. The jury returned a verdict for the United States condemning the goods seized; and a judgment of forfeiture followed. On appeal by the owners, the argument was made that the court order directing production of the invoice and the reception of the invoice in evidence was violative of the Fourth Amendment. The Supreme Court, in reversing the judgment below and awarding a new trial, said that "a compulsory production of a man's private papers to establish a criminal charge against him, or to forfeit his property, is within the scope of the Fourth Amendment to the Constitution, in all cases in which a search and seizure would be, because it is a material ingredient, and effects the sole object and purpose of search and seizure."

The statute involved in the *Boyd* case provided that the offender, bringing goods into the United States in violation of its custom laws, might be punished by fine or by forfeiture of the imported goods. The basis of decision was that the case was criminal in character. The Supreme Court did not consider whether or not the initial seizure of the goods constituted a search and seizure within the purview of the Fourth Amendment, but directed its attention only to the court order requiring production of private papers. Nor did the Court decide that the order was equivalent to a search warrant which must be supported by oath. The ruling was merely that the order for the production of the invoice was, under the Fourth Amendment, unreasonable in the circumstances of the case. The issue of verification was not involved.

[*Libel Is Civil Action*]

No order for the production of private papers is involved in the instant case. Nor is this proceeding, in any aspect, a criminal case. An ordinary libel *in rem* brought by the United States is undoubtedly a civil action. *United States v. LaVengeance*, 3 Dallas 297, 301; *Dobbins's Distillery v. United States*, 96 U. S. 395, 399.

[*No Search or Invasion of Privacy*]

There is no element of search or invasion of the privacy of the citizen or of his home involved in the case at bar. The proceeding here is for the condemnation of adulterated goods under authority of an Act of Congress, by libel *in rem* to bring into court the thing charged as deleterious for determination of the issue of whether it is fit food, or not.

[*Power of Congress Under Commerce Clause*]

Under the interstate commerce clause of the Constitution, Congress has been vested with full power to keep the channels of interstate commerce free from the transportation of illicit or harmful articles, and to make those deleterious to public health "outlaws of such commerce." So long as the means are appropriate to that end and do not violate any provision of the Constitution, Congress may be the judge of the means to be employed in exercising its powers. *McDermott v. Wisconsin*, 228 U. S. 115, 128. See, also, *Hipolite Egg Co. v. United States*, 220 U. S. 45; *Seven Cases of Eckman's Alterative v. United States*, 239 U. S. 510, 514.

[*"Warrant"*]

No significance should be attached to the use by the Supreme Court of the words "warrants of arrest" in the Admiralty Rules which it has promulgated. The usage bears no semblance to the use of the word "warrant" in the Fourth Amendment. In admiralty, the term "arrest" is the technical term long sanctioned to indicate an actual seizure of property. *Pelham v. Rose*, 9 Wallace 103, 107.

[*Libel Not Search and Seizure*]

The United States District Court for the Western District of Virginia has correctly held that a libel *in rem* under the Federal Food, Drug, and Cosmetic Act is not a search and seizure within the meaning of



the Fourth Amendment, and that the libel information need not be verified. *United States v. Eighteen Cases of Tuna Fish*, 5 F. (2d) 979. See, also, *United States v. Two Barrels of Desiccated Eggs*, 185 Fed. 302 (D. C. Minn.). The contrary has been held erroneously in *United States v. Eight Packages and Casks of Drugs*, 5 F. (2d) 971 (S. D. Ohio).

[Order of District Court Reversed]

As has been demonstrated, the libel of information filed by the United States Attorney on behalf of the United States in the instant proceeding required no verification; and the seizure of the alleged adulterated articles in interstate commerce, in the man-

ner prescribed by the Federal Food, Drug, and Cosmetic Act, U. S. C. A., Title 21, Sec. 334, was not an unreasonable search and seizure in contravention of the Fourth Amendment to the Constitution of the United States. The District Court erred in entering its order of March 10th, sustaining the motion to quash the writ of attachment, ordering the goods seized returned to appellee, and dismissing the complaint. That order is therefore reversed; the motion of the appellee filed in this court to dissolve the stay order entered by the District Court on March 17, 1943, is denied; and the cause is remanded to the District Court for further procedure in conformity with this opinion.

UNITED STATES OF AMERICA v. 284 BARRELS, MORE  
OR LESS, OF DRIED EGGS, LABELED IN PART  
"SPRAY DRIED WHOLE EGG JOE  
LOWE CORP.\*\*\*"

United States District Court for the Western District of Tennessee, Western  
Division. Civil Action No. 506. Filed July 29, 1943. 52 F. Supp. 661.

From tests made by the Food and Drug Administration, it was found that the dried eggs proceeded against contained lactic acid, acetic acid, formic acid, and bacteria in amounts greater than the amounts contained in good dried eggs. The dried eggs were held to be adulterated in that they consisted wholly or in part of a decomposed substance, rendering them unfit for food in any manner.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Tests relating to the sense of taste and smell, referred to as the organoleptic test, to which the dried eggs proceeded against had been subjected, established that the eggs were repulsive and a sour, decomposed product.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

**Findings of Fact, Conclusions of Law and  
Order for Decree**

MARION S. BOYD, District Judge: The Court makes the following:

*Findings of Fact*

I. The United States Government, through libel proceedings, seized two hundred and eighty-four barrels of dried eggs at Memphis, Tennessee. The question, purely one of fact, is whether or not they are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (Title 21 United States Code Annotated, Section 342 (a) (3)), and more particularly whether they consist wholly or in part of a decomposed substance.

II. These eggs, the property of claimant Joe Lowe Corporation, were processed at claimant's plant in San Antonio, Texas.

III. Samples were taken at San Antonio, Texas, and at Memphis, Tennessee, for analysis in Government laboratories and by experts in the employ of the claimant herein.

IV. The United States Government, through its Food and Drug Administration, made numerous tests and experiments to arrive at a basis for standards in the matter of judging dried eggs and detecting decomposition therein. Thus, it was determined that in good, edible, liquid eggs, and in dried eggs made therefrom, the micro-



scopic bacterial count is relatively low; while in eggs which are allowed to undergo souring before drying, such counts greatly increase. Also, it was determined that the amounts of lactic and acetic acids in dried whole eggs made from good, edible liquid eggs are relatively small, with no formic acid; while in eggs which are allowed to undergo souring before drying the amounts of lactic and acetic acids are significantly greater, and substantial amounts of formic acid are found in the dried egg powder made therefrom.

V. From the tests and experiments set out above, it was determined that a sour egg is one which has undergone bacterial deterioration.

VI. From the tests and experiments made by the Food and Drug Administration aforesaid, it was found that lactic acid in good eggs never exceeds fifty milligrams per one hundred grams of dried eggs. It was also found that acetic acid in good eggs never exceeds sixty-five milligrams per one hundred grams of dried eggs. Further, that formic acid is not found at all in good eggs.

VII. From the tests and experiments made by the Food and Drug Administration, it was determined that dried eggs containing more than one hundred million bacteria per gram are sour and contain decomposed substance. It was also established that as a general rule as the bacterial microscopic count increases, there is a corresponding increase in the amount of acid present.

VIII. As a result of the microscopic bacteriological count on samples of the dried eggs in this case, it is found that the eggs contain from one hundred and twenty-two million bacteria per gram to a maximum of four billion, six hundred and ten million bacteria per gram.

IX. As a result of the chemical analysis of the samples of the dried eggs in this case, it is found that they contain in formic acid from twenty-seven milligrams per one hundred grams to a maximum of one hun-

dred and seven milligrams per one hundred grams; that they contain from sixty-one to one hundred and forty-six milligrams per one hundred grams of acetic acid; and that they contain from eighty-six to six hundred and two milligrams per one hundred grams of lactic acid.

X. The tests relating to the sense of taste and smell, referred to as the organoleptic test, to which the eggs in this case were subjected, establish that the eggs under investigation herein are repulsive and a sour, decomposed product.

XI. The practices and conditions under which the eggs involved herein were processed were not conducive to the production of a good, wholesome and edible product, but were such that sour or decomposed eggs could be reasonably expected to result. In this connection, eggs, including those under investigation here, on being broken were accumulated and permitted to remain in the breaking room at high temperatures for unreasonable lengths of time before refrigeration. The proof shows also that frozen eggs, from which the eggs in this case were dried, were taken from a warehouse lot which contained a substantial quantity of sour, decomposed eggs.

XII. From all of the tests made in this case, and from all the facts and circumstances, the Court finds the eggs herein to be sour, and, therefore, to contain a decomposed substance, which renders them unfit for food in any manner.

#### *Conclusions of Law*

I. The eggs herein are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code Annotated, Section 342 (a) (3)), in that same consist wholly or in part of a decomposed substance rendering them unfit for food in any manner.

II. The United States of America is entitled to a decree of condemnation as prayed, with costs.

#### *Order for Decree*

Counsel will prepare and submit appropriate decree.



**UNITED STATES v. 143 PACKAGES, MORE OR LESS,  
EACH CONTAINING 3 BOTTLES OF NUE-OVO**

United States District Court for the Western District of Washington, Southern Division. No. 7408. August 26, 1943. 51 F. Supp. 1.

The jury found "Nue-Ovo" misbranded by reason of false and misleading claims made in the labeling that the product was of value in the treatment of arthritis. On claimant's objection to the form of the decree of condemnation providing for the destruction of the product, it was held that the language of the Act is unambiguous, and clearly places it within the discretion of the court to dispose of condemned property either by ordering its sale or destruction, so long as the disposition is in accordance with the provisions of the Act.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

In passing upon the matter, the facts found by the jury's verdict must be accepted. Since the jury had found that there was a misbranding and that the article had no therapeutic value in the treatment of arthritis, it would be an abuse of discretion on the part of the court to direct the sale of the product and thus permit it to become again an article of commerce.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

J. Charles Dennis, U. S. Attorney; Harry Sager, Assistant U. S. Attorney; Tacoma, Wash.; for libelant and plaintiff.

Eisenhower, Hunter and Ramsdell, Tacoma, Wash.; Harry G. Hoy, Portland, Ore.; for intervenor and defendant.

*[Nature of Proceeding]*

CHARLES H. LEAVY, District Judge: This is a libel proceeding instituted by the United States of America under the provisions of the Federal Food, Drug, and Cosmetics Act, 21 U. S. C. A., against 143 packages, more or less, each containing three bottles of a proprietary medicine called "NUE-OVO," which were claimed by Research Laboratories, Inc., as being their property.

*[Proceedings in Case]*

The method of labeling in this case was novel and unusual in practice. The sufficiency of the government's libel of information was attacked by the intervenor herein on the ground that it did not state facts sufficient to show a violation of the Federal Food, Drug, and Cosmetic Act. After amendment by the government of its original libel of information, the attack was renewed upon the same grounds, and the intervenor's motion to dismiss was sustained by the District Court. Thereupon, the government appealed, and the holding of the District Court was reversed and the cause remanded for trial upon the allegations of the amended libel and the issues made by the further pleadings of the intervenor. *U. S. v. Research Laboratories, Inc.*, 126 Fed. (2d) 42.

Trial upon the issues as made by the

pleadings was by jury, resulting in a verdict finding for the government in its contention that the articles were misbranded by reason of the labeling thereof being false and misleading.

Following the receipt and entry of the verdict herein, plaintiff submitted, upon notice, a form of judgment and decree of forfeiture and condemnation, providing that the United States Marshal shall destroy the said 143 packages of "Nue-Ovo."

*[Contention of Intervenor]*

At the time fixed by the notice for the presentation of the judgment, the intervenor, Research Laboratories, Inc., appeared and objected thereto, insisting that that part of the decree providing for the destruction of the libeled property should be stricken, and in lieu thereof, a provision made for the sale of the property. The parties requested and were given time to submit written briefs upon this issue.

It is the contention of the intervenor, Research Laboratories, Inc., that under the facts as disclosed in this case, the court is without discretion to order the destruction of the property, and they contend further that if such discretion, as a matter of law, does exist, it would be an abuse thereof, as well as unjust and inequitable to order its destruction.



*U. S. v. 650 Bags Roasted Malted Cereal**[Statutory Provision]*

The language of the Act is unambiguous, and clearly places it within the discretion of the court to dispose of the condemned property either by ordering its sale or destruction, so long as the disposition is in accordance with the provisions of the Act. 21 U. S. C. A. 334 (d).

*[Other Cases]*

The conclusion reached here as to the discretionary power of the court in reference to the disposition of condemned property is supported by the following cases: *U. S. v. Two Cans of Oil of Sweet Birch and Three Cans of Oil of Gaultheria*, 268 Fed. 866; *U. S. v. 1443 Cases, More or Less, Canned Salmon*, 7 Fed. Supp. 77.

*[Jury's Findings]*

In making a disposition of this matter, the court is bound by the facts as they were found by the jury, upon the issues submitted to it. The issue made by the pleadings and directly submitted by the court's charge to the jury for its consideration was whether there was a misbranding by reason of the labeling being false or misleading, and this, in turn, included the issue as to whether the medicine involved herein had any value whatever in the beneficial treatment of arthritis in any of its forms.

It was conceded by all parties that "Nue-Ovo" was not injurious or harmful. The verdict of the jury is the equivalent of a finding:

1. That the labeling of "Nue-Ovo" was false and misleading.

2. That the substance "Nue-Ovo" was useless and valueless as a remedy in the treatment of arthritis.

*[Jury's Verdict as to Facts Must Be Accepted]*

In passing upon the matter now before the court, therefore, it is not a question of what the court may think concerning the facts, but the facts that were found by the jury's verdict must be accepted, and since the jury has found that there was a misbranding by reason of false and misleading labeling, and also found that the article in question has no therapeutic value in the treatment of arthritis, it would be an abuse of discretion on the part of the court to direct its sale, and thus permit it to again become an article of commerce.

*[Condemnation Proper]*

The only purpose of placing "Nue-Ovo" on the market was as a beneficial treatment for arthritis. The findings of the jury to the effect that it was not such treatment make it inconsistent to direct its sale and movement back into the channels of commerce and trade.

I, therefore, overrule the objections interposed by the intervenor, Research Laboratories, Inc., and upon the re-submission of the judgment and decree of forfeiture and condemnation, the same will be signed.

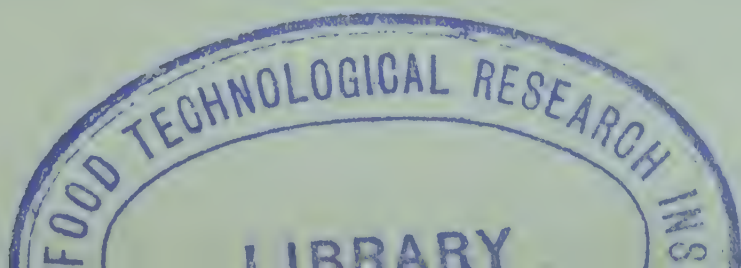
The Clerk of this Court will notify the attorneys for the parties of the filing of this Opinion.

UNITED STATES v. 650 BAGS OF ROASTED MALTED  
CEREAL, AND 100 CASES OF MALTED  
BEVERAGE CEREAL

United States District Court for the Western District of Missouri. December 2, 1943. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 6403) Issued June 1945.

Seizure proceedings were instituted against roasted malted cereal and malted beverage cereal on the grounds that the statement "A Coffee Substitute" on the label was false and misleading, and that the label failed to bear the common name of the product, roasted malted barley. It is well known that no cereal can be utilized to produce a coffee substitute, that a substitute must contain qualities akin to that of the article for which substituted, and that cereal coffee is not a substitute for genuine coffee.

Sections 304 (a), 403 (a), 403 (i), Federal Food, Drug, and Cosmetic Act.





*[Contention of Intervenor]*

REEVES, District Judge: It is contended by the intervenors that the amended libel fails to state a cause of action for the forfeiture of either one of the articles mentioned therein and moreover that the amended libel lacks definiteness and fullness in the respect that the misbranding asserted is not set out with particularity. In addition to the above, one of the intervenors charged that the libel did not assert it had moved one of the articles complained against in interstate commerce.

*[Charges of Libel]*

The amended libel charges the violation of subsection (a) Section 343, Title 21 U. S. C. A. and subdivision (1) of subsection (i) of said section. Subsection (a) provides in substance that "a food shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular." Subdivision (1) of subsection (i) of said section provides as follows with respect to the label, "if it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be."

It is charged in the libel that 650 bags, more or less, of "Froemco Roasted Malted Cereal" and 100 cases, more or less, "Brazilian Style MO-JV A Malted Beverage Cereal" not only moved in interstate commerce but were misbranded by reason of a designation that they were a coffee substitute. It is stated in the libel that in truth and in fact such products were malted, roasted, ground barley.

1. The amended libel is commendably brief in compliance with procedural rules. It contains a direct charge that both articles enumerated were falsely branded and that such branding was misleading. The 650 bags were marked "Froemco Roasted Malted Cereal." There was no designation as to the kind of cereal. The 100 cases were designated as "Brazilian Style MO-JV A Malted Beverage Cereal."

*[Cereal Coffee Not a Substitute for Genuine Coffee]*

It will be noted from this that such product was designated as a cereal product. Nevertheless it contained a label that it was a "coffee substitute." It is well known that no cereal can be utilized to produce a coffee substitute. A substitute according to the weight of authorities must contain qualities

akin to that of the article for which substituted. According to Webster's Dictionary, a substitute as used in this case would mean a "thing put in place of another." Cereal coffee is not a substitute for genuine coffee.

*[Other Cases]*

In the case of *E. C. Hazard & Co. v. United States*, 164 Fed. 907, the district court for the Southern District of New York followed the opinion of one of the general appraisers with respect to a tax on an alleged coffee substitute. In that case the liquid extract had actually been taken from the coffee bean. It was contended by the owner that it was a coffee substitute. Both the board of appraisers and the court held that it was not.

In the case of *Ex parte Hunnicutt*, 123 Pac. 179, 1. c. 185, 7 Okla. Cr. 213, the court held that an alleged substitute for malt liquor could not be considered as a substitute unless it contained a forbidden quantum of alcohol "measured by volume."

*[Requisite of Substitute; Common or Usual Name Required]*

A substitute should possess some of the qualities of the article for which it is substituted. The article may have been branded a coffee cereal but not a coffee substitute. The statute required that the label shall disclose the common or usual name of the food.

The intervenors did not comply with this statutory requirement where it referred to the product as a "malted beverage cereal." There are many cereals from which such products may be made. It would have been a simple matter for the intervenors to have designated these products as malted and roasted ground barley, as alleged in the libel.

*[More Particular Statement of Facts Unnecessary; Libel Sustained]*

2. The intervenors are familiar with the libeled product; they know the nature of the product and how it has been branded. The government should not be called upon to make a fuller or more particular statement of facts with which both sides are entirely familiar. The labels are both false and misleading. It would follow that the libel should be sustained.



[*Sufficient that Product Moved in  
Interstate Commerce*]

3. One of the intervenors pointed out in its exception that it did not cause the alleged offending articles to be moved in interstate commerce. The proceeding is against the articles themselves, which is a proper procedure, and the libel contains an appropriate averment that the products were in fact moved in interstate commerce. This was sufficient.

[*Exceptions to Libel Overruled*]

In view of the above, the exceptions to the libel are overruled and the intervenors will be allowed 20 days to plead further.

[An answer having been filed denying that the labeling was false and misleading in any respect or that it did not contain the common or usual name of the product, the court, on February 3, 1944, handed down findings of fact and conclusions of law to the effect that the statement in the label

which represented that the product was a coffee substitute would mislead prospective purchasers into believing that the product had a stimulating ingredient such as caffeine and had the taste of coffee; and that the statement designating the product as a coffee substitute was false and misleading as the product was not useful as a coffee substitute; and that roasted malted cereal was not a common or usual name of roasted malted barley. The court concluded that the article was misbranded since it was not a coffee substitute and the label failed to describe the product by its common or usual name.]

[On February 4, 1944, judgment of condemnation was entered, and on February 14, 1944, the Klop Sales Co., having appeared as claimant, the product was ordered released under bond to be used in making animal feed under the supervision of the Food and Drug Administration.]

---

**SEKOV CORPORATION v. UNITED STATES**

United States Circuit Court of Appeals for the Fifth Circuit.

No. 10487. December 8, 1943. 139 F. 2d 197.

Affirming 45 F. Supp. 52. See page 22.

Properly admitted testimony of practicing physicians clearly established that Sekov Reducer was not a remedy for obesity, that it would not reduce a stout woman to the slender proportions shown in the picture on the container, that the directions for use were inadequate, and that its use was dangerous to health when used as directed on the label.

Sections 304 (a), 304 (b), 502 (f), 502 (j), Federal Food, Drug, and Cosmetic Act.

The fact that the claimant had been proceeded against previously by the Federal Trade Commission did not bar inquiry by the District Court into questions presented by the libel, since the issues were not identical. Moreover, the power and duty of the District Court to condemn the misbranded articles were not impaired or diminished by the former Federal Trade Commission proceeding.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

William M. Ryan, Houston, Texas, for appellant.

William R. Eckhardt, III, Assistant U. S. Attorney, Houston, Texas, for the United States.

Before SIBLEY, HUTCHESON, and McCORD, Circuit Judges.

[*Facts of Case*]

McCORD, Circuit Judge: The appeal is from a judgment condemning fifteen cartons of Sekov Reducer, an alleged remedy for obesity. The trial court found that the product had been falsely labeled and misbranded and shipped in interstate commerce contrary to the provisions of the Federal,

Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 301, *et seq.*, § 334, § 352 (a), (f), and (j). The findings of fact and conclusions of law of the trial court are included in a published opinion, *United States v. Fifteen Cartons, More or Less, of Sekov Reducer*, 45 F. Supp. 52.



The Sekov Reducer containers bore a picture of a woman with a slender figure. Printed booklets intended for distribution with the product were titled "Sekov, A Path to Slenderness." The labels on the packages, and the booklets which appellant alleges were distributed to purchasers, were false and misleading in that they represented Sekov Reducer to be a safe and appropriate treatment for the reduction of weight.

*[Proof of False Claims, Inadequate Directions, and Dangerous Nature]*

Properly admitted testimony of practicing physicians clearly establishes that Sekov Reducer is not a remedy for obesity; that it will not, as claimed, reduce the figure of a stout woman to the slender proportions shown in the picture on the container; that directions for use of the product were inadequate; and that its use is dangerous to health when used with the frequency or duration prescribed in the directions on the label, "and this is true whether the patient

is or is not suffering from hyperthyroidism or from hypothyroidism."

*[Power of Court To Condemn Not Impaired by FTC Inquiry]*

Appellant Sekov Corporation contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government's libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District Court to condemn the misbranded articles was not impaired or diminished by the former proceeding. *United States v. Research Laboratories*, 126 F. 2d 45.

*[Judgment of Condemnation Affirmed]*

The findings of the District Court are supported by the evidence and its judgment is in accordance with the applicable law.

The judgment is

AFFIRMED.

## UNITED STATES v. 149 GIFT PACKAGES

Labeled in Part (Sticker on Cellophane-Wrapped Package)  
 "Ingredients; Sugar, Corn Syrup, Flour, Malt, Nuts,  
 Cocoanut and Creamery Butter, Condensed Milk,  
 Shortening, Leavening Cr. of Tart., Citric  
 Acid, Nat. and Art. Flav. U.S. Cert.  
 Col.\*\*\* Net 1 lb. 2 oz."

United States District Court for the Eastern District of New York.

Miscellaneous No. 827. December 11, 1943. 52 F. Supp. 993.

The theory of the Federal Food, Drug, and Cosmetic Act is obviously that seized articles have themselves violated the law, and this is an issue of fact. Either party, under the statute, may demand a jury trial.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

In view of the right to a jury trial, and the fact that the burden of proof lies on the Government to sustain the libel, it is difficult to see how the requirements of due process are evaded by the Act.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The conventional method of testing the legal sufficiency of a libel is by filing exceptions thereto (Admiralty Rule 27), and should be followed if the Government is proceeding by methods not sanctioned by the Constitution.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

A counterclaim interposed by the claimant in a seizure suit based on Section 403 (d) requested a declaratory judgment to establish the unconstitutionality of the statute. While the counterclaim did not in terms ask for an injunction, if the declaration which it sought were made, there would be in effect a decision upon the constitutionality of a Federal statute, having the same effect as an injunction.

Sections 304 (a), 304 (b), 403 (d), Federal Food, Drug, and Cosmetic Act.



Harold M. Kennedy, U. S. Attorney (Morris K. Siegel of counsel), Brooklyn, N.Y.; for libelant.

David Haar, New York, N.Y., for claimant.

*[Facts of Case]*

BYERS, District Judge: Motion to strike counterclaim.

In this cause the Government has libeled 149 Gift Packages of food stuffs, alleging them to be misbranded. They have been claimed by R. L. Albert & Son, Inc., in an answer which denies the alleged misbranding.

The claimant does not in terms, except in the counterclaim, admit that it shipped the 149 Gift Packages in interstate commerce, although perhaps it meant to do so by inference, since so much of the libel is not denied. This does not meet the requirements of Admiralty Rule 26.

The answer does deny misbranding within Title 21, U. S. C. (A.), § 343 (d), which provides that a food shall be deemed to be misbranded "(d) If its container is so made, formed, or filled as to be misleading", which is charged in the libel.

The answer contains a subdivision entitled "Complete Defense and as a Counterclaim", which recites the claimant's corporate status and business; the enactment by Congress of the statute under which the libel is filed; the seizure of these packages in California and the consent to transfer the proceedings thereby initiated to this Court, and that the Federal Security Agency (charged with the enforcement of this law) has threatened similar proceedings elsewhere. That the statute is unconstitutional in that it deprives the claimant of its property without due process of law.

It is alleged that, as the result of these matters, there is a controversy existing between the United States of America and the claimant as to whether the enforcement of the Federal Food, Drug, and Cosmetic Act does or does not unconstitutionally deprive the claimant of its property, and hence a declaratory judgment is sought to establish the unconstitutionality of the statute and the remedies thereunder.

The libelant has moved to strike the counterclaim as being inappropriate to a proceeding which, as nearly as may be, is to conform to the procedure in Admiralty (Title 21 U. S. C. (A), § 334 b).

*[Due Process]*

The theory of the statute is obviously

that the seized articles of food have themselves violated the law, and this is an issue of fact. "Upon demand of either party any issue of fact joined in any such case shall be tried by jury." (§ 334 b.)

In view of that provision, it is difficult to see how the requirements of due process have been evaded. Manifestly the burden of proof lies upon the Government to sustain the material allegations of the libel, once issue is joined upon the merits.

*[Declaratory Judgment]*

As to the availability of the declaratory judgment statute (Title 28 U. S. C. (A) § 400) in a proceeding in Admiralty, there seems to be no decision which the Court has been able to find, nor have counsel cited any.

*[Exceptions]*

The conventional method of testing the legal sufficiency of the articles in a libel is by filing exceptions thereto (Admiralty Rule 27); and that course has been found adequate by many years of experience.

It is open to this claimant, and should be followed if it be advised that the Government is seeking to proceed herein according to methods not sanctioned by the constitution.

*[Declaration Similar to Injunction]*

While the counterclaim does not in terms ask for an injunction, if the declaration which it seeks were to be made, there would be in effect a decision upon the constitutionality of a federal statute, having the same force and effect as an injunction, and it might well be argued, I think, that Title 28 U. S. C. (A), § 380 a, ought to be applicable to such a situation.

*[Counterclaim Stricken]*

It has not been shown to the satisfaction of this Court, that a multiplicity of suits involving the same issue is threatened, nor can it be said that the make-up or constituency of these particular packages is an issue of such important legal scope that the otherwise non-conforming pleading should be allowed to stand.

Motion to strike the counterclaim is granted, without prejudice to the claimant's rights to challenge the libel by appropriate exceptions.

Settle order.



UNITED STATES v. 55 CASES POPPED CORN, 20 CASES POPCORN,  
 25 CASES POPCORN, 25 CASES POPCORN

United States District Court for the District of Idaho, Central Division.  
 No. 1551. December 20, 1943. 62 F. Supp. 843.

The Act was passed to protect the public health and should be construed liberally.

Title, Federal Food, Drug, and Cosmetic Act.

Seizure proceedings were instituted against popcorn containing mineral oil. The label of the packages set forth the ingredients, including the mineral oil. The Government charged that the product was adulterated and misbranded by reason of the presence of mineral oil. The court was satisfied that there was no established formula for popcorn, and that the product involved was popcorn.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

The consumer was fully advised as to the ingredients, including the mineral oil; no misbranding was involved.

Sections 304 (a), 403 (b), Federal Food, Drug, and Cosmetic Act.

Since there was no evidence showing that mineral oil in the quantities used would be injurious to the public health, and inasmuch as no reason was shown why popcorn as prepared with mineral oil and branded truthfully should not be consumed by the public, the popcorn could not be found to be adulterated.

Section 402 (b), Federal Food, Drug, and Cosmetic Act.

John A. Carver, U. S. District Attorney; E. H. Casterlin, Assistant U. S. District Attorney; R. W. Beckwith, Assistant U. S. District Attorney; all of Boise, Idaho, for plaintiff.

Hamblin, Gilbert and Brooke, Spokane, Wash., for Mason, Ehrman & Co.

*[Adulteration Alleged]*

CLARK, District Judge: The libel of information in this case seeks destruction of four interstate shipments of popped corn charged to have been adulterated within the meaning of 21 U. S. C. A. in that:

"342 (b) (1) in that a valuable constituent, namely butter or an edible vegetable oil, has been in whole or in part omitted;"

"342 (b) (2) in that a substance consisting of popped corn with added artificially colored non-nutritive mineral oil and salt has been substituted for popcorn (or popper corn) which the article purports to be;"

"342 (b) (3) in that inferiority has been concealed by the addition of artificial color;"

"342 (b) (4) in that mineral oil has been mixed or packed therewith so as to reduce its quality or strength or make it appear better or of greater value than it is;"

"343 (b) in that it is offered for sale under the name of 'popped corn' (55 cases) and 'popcorn' (20 cases and the two 25 cases), the same being the name of an-

other food, 'popped pop corn', to which has been added melted butter or vegetable oil".

The Government relies mainly on subsection 343 (b) and contends under this subsection that the corn in question was not popped popcorn because melted butter or vegetable oil was not used in preparing it for the market. In other words, that popped popcorn has a definite and distinct definition and that if any other ingredients were added to popped popcorn than butter or vegetable oil, it was not popped popcorn, and in view of the fact that in the instant case, mineral oil was used, it was an adulterated food.

This libel is brought under subdivision (b) of Section 342 Title 21 U. S. C. A.,—the Food and Drug Act, which is as follows:

"(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any man-



*U. S. v. 55 Cases Popped Corn*

ner; or (4) if any substance has been added thereto or mixed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

*[Food and Drug Act To Be Construed Liberally]*

The Food and Drug Act was passed to protect the public health and should be construed liberally to meet the purpose for which it was enacted and the Court must endeavor to protect the public from interstate commerce in food products so adulterated as to injure or endanger health and also to see to it that food products are so branded that the consumer would know that there was no misrepresentation as to its substance and that the food purchased was what it purported to be.

*[No Misbranding Involved]*

The popped corn in question was branded plainly on each package as follows:

"Masterson's Food Products Popped corn Ingredients: Popcorn, Mineral Oil, Salt (if colored or flavored) U. S. Certified coloring and flavoring used. \* \* \* Masterson Food Products Co., Spokane Washington. Net Weight 5 ounces when packed."

The only change in the branding on the various packages being as to the weight, which was according to the size of the package. So in the first instance there is no misbranding and the consumer was fully advised as to the contents of the various packages. There was no deceit practiced in this matter and there is no contention on the part of the Government that there was. So it leaves only two questions for the Court.

*[Questions for the Court]*

First, is the food product in question popped popcorn?

Second, has any valuable constituent been in whole or in part abstracted therefrom, or has any substance been substituted in whole or in part therefor, or is there any damage or inferiority that has been concealed in any manner, or has any substance been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength, or make it appear better or greater than it is?

*[Article Is Popped Popcorn]*

I can see little merit in the contention that the article of food contained in the packages branded as hereinbefore stated was not popped popcorn. It would be just as reasonable to say that if the corn so popped had not had salt, butter or vegetable oil used in its manufacture and preparation that it would not have been popped popcorn, and it is plain from the evidence introduced in this case that there is no exact formula used in the preparation of popcorn for the market. In the case of *W. B. Wood Mfg. Co. v. United States*, 292 Fed. 133, the Court said: "The standard set by the statute is not what is customarily done by manufacturers but what is properly done by them \* \* \*" Whether mineral oil has ever been used heretofore, the Court is not advised but the Court is satisfied that there is no established formula for its preparation, and the Court is also satisfied that the corn in question is popped popcorn, and so holds.

*[No Reason Shown Why Mineral Oil Should Not Be Used]*

On the second question there is no evidence before the Court showing that mineral oil in the quantities used would be injurious to the public health, nor is there any reason shown why the popcorn as prepared and branded should not be consumed by the public, nor that it is adulterated within the meaning of the statute, and as there is no proof of these facts, the popped corn could not be found to be adulterated within the meaning of the statute.

*[Libel Dismissed as Not Supported by Evidence]*

Realizing full well the duty of the Court to protect the public from interstate commerce in food products injurious to the public health and having in mind the importance of the strict enforcement of the Food and Drug act, and giving the most liberal construction to the Government's case, the Court is of the opinion that the libel of information is not supported by the evidence and should be dismissed. An order will be entered.



## UNITED STATES v. 379 BOTTLES AND 102 BOTTLES OF GRAYVITA

United States District Court for the Northern District of Illinois. December 22, 1943. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7905) Issued January 1946.

A seizure action was instituted in the District of Colorado charging that the product was misbranded. On motion by the claimant, the case was ordered removed to the Northern District of Illinois, where the claimant had its principal place of business. The files, papers, etc., were removed to that district, and the claimant filed its answer. Subsequently, on motion of the Government, the District Court for the District of Colorado vacated its removal order and transferred the cause to the Southern District of Illinois. Since both orders had been rendered at the same term of the District Court for the District of Colorado, it would be assumed that the first order was still in the breast of the court at the time of the making of the second order and that the second order was valid.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

*[Case Removed to Northern District of Illinois On Motion of Claimant]*

BARNES, District Judge: On May 24, 1943, a libel for condemnation was issued out of the District Court of the United States for the District of Colorado against 479 bottles of "Grayvita." On July 24, 1943, a motion was made by the claimant in the District Court of the United States for the District of Colorado at Denver to remove and transfer the said cause to the Northern District of Illinois, Eastern Division, and an order was made on that day transferring and removing the cause to the District Court for the Northern District of Illinois, Eastern Division. Pursuant to the order of July 24, 1943, the clerk of the court for the District of Colorado caused a physical transfer and removal of all papers, documents, complaint and information in said cause to the clerk of the District Court of the United States for the Northern District of Illinois, Eastern Division, and the clerk of this court filed and docketed said cause. Subsequently, the claimant filed its answer and the cause was set for trial in this court.

*[Cause Transferred to Southern District of Illinois On Motion of Government]*

On August 18, 1943, on motion of the United States Attorney for the District of Colorado, the District Court for that district, vacated its previous order of July 24, 1943, and transferred the cause to the District Court of the United States for the Southern Division of Illinois at Springfield, Illinois, and ordered the clerk of this court to transfer and remove the cause from Chi-

cago, Illinois, to the District Court Southern Division at Springfield, Illinois.

*[Jurisdiction to Issue Second Order Questioned]*

It seems that the United States desires to try its case in Springfield, Illinois, while the defendant desires to try the case in Chicago, where it says it has its principal place of business. The court would very much dislike a controversy either with the District Court for the District of Colorado or with the District Court for the Southern District of Illinois. The defendant questions the jurisdiction of the District Court for the District of Colorado to make its second order. No case directly in point has been called to the attention of the court.

*[Second Order Valid]*

The court will assume that since the orders of July 24, 1943, and August 18, 1943, were both rendered at the same term of the District Court for the District of Colorado, the first order was still in the breast of the court at the time of the making of the second order, and, accordingly, the second order was valid. Had this court proceeded to dispose of the case prior to the making of the second order it is possible that a different question would be presented.

*[Transmittal of Records to Southern District of Illinois]*

The clerk of this court is directed to transmit to the clerk of the District Court for the Southern District of Illinois, at Springfield, Illinois, all records in this case



*U. S. v. 184 Barrels Dried Whole Eggs*

that were received by him—in accord with the second order of the District Court for the District of Colorado, above referred to.

[On March 24, 1945, the Carlay Co. having notified the court that it would not con-

test the action further, and having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.]

**UNITED STATES v. 184 BARRELS DRIED WHOLE EGGS  
SAME v. 47 BARRELS DRIED WHOLE EGGS  
SAME v. 5 BARRELS DRIED WHOLE EGGS**

United States District Court for the Eastern District of Wisconsin. Civil Actions Nos. 852, 853, and 1111. December 22, 1943. 53 F. Supp 652.

Under terms of a contract between the claimant and a Government corporation, the claimant agreed to supply dried whole eggs, but the contract provided for inspection by the Government prior to the delivery date. Where the eggs were rejected after inspection, no shipping instructions were given or bill of lading issued, and additional marking and labeling remained to be added, it was held that the eggs had not been introduced into interstate commerce.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

While the seizure action was pending, a separate suit for injunctive relief could have been commenced in the same court, and it would have been appropriate for the court to have ordered a consolidation.

Sections 302 (a), 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Where a party is before the court in an *in rem* proceeding, the court has the power to render an *in personam* judgment against him. The court should exercise such power where it will further the ends of justice, eliminate multiplicity of actions, and save expense to the parties.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Amendment by the Government of the prayer for condemnation should be permitted where the amendment sought to add, against a resident defendant already before the court, an alternate prayer for injunctive relief, since the allowance merely dispensed with personal service which could have been had at any time.

Sections 302 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The Act must be construed to prohibit the interstate shipment of food when it consists in whole or in part of any filthy, putrid, or decomposed substance, irrespective of whether it is fit for food or injurious to health.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The Government had not sustained the burden of proof upon it to establish that the product proceeded against was decomposed.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

B. J. Husting, U. S. District Attorney, Milwaukee, Wis., for plaintiff.

William J. McCauley, Milwaukee, Wis., for defendant.

*[Nature of Action]*

F. RYAN DUFFY, District Judge: This case is a consolidation of three *in rem* proceedings under Sec. 304 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C.,

Sec. 344 (a)). The claimant, Wisconsin Dried Egg Company of Oconto, Wisconsin, filed an answer denying that the eggs in actions Nos. 852 and 853 were in interstate commerce, and further denying adulteration in all three proceedings.



*[Seizure Provisions of Federal Act]*

Sec. 304 (a) of the act provides:

"Seizure. Any article of food . . . that is adulterated or misbranded when introduced into or while in interstate commerce, . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: . . ."

*[Products in Two of Three Cases Not in Interstate Commerce]*

The eggs had been gathered by claimant from within the State of Wisconsin and were processed at claimant's plant in this State. The five barrels in Action No. 1111 were shipped to Chicago, Illinois, and there seized, and of course were in interstate commerce. However, the eggs in Actions Nos. 852 and 853 have never been outside the State of Wisconsin. They have never been offered to a common carrier for shipment, and in fact never left the property of the claimant. Under the terms of the contract between the claimant and the Federal Surplus Commodity Corporation, the claimant agreed to supply a certain number of pounds of spray dried whole eggs, but the contract provides for inspection by government agents prior to the delivery date. After inspection the eggs in question were rejected. No shipping instructions were ever given and no bill of lading was ever issued. Additional marking and labeling remained to be added. It is my opinion that the eggs in Actions Nos. 852 and 853 had not been introduced into and were not in interstate commerce.

*[Amendment Seeking Injunctive Relief Permitted]*

At the commencement of the trial, after the court had expressed doubt on the jurisdictional question of interstate commerce, plaintiff's attorney moved that the prayer for condemnation be amended by the addition of an alternate prayer for injunctive relief, in the event that the prayer for condemnation were denied on jurisdictional grounds. The government and the claimant were in court ready to present their witnesses on the merits. Both prayers for relief grew out of the same transaction. The basic issues of adulteration were identical. If the court ruled adversely to the government on the jurisdictional question, it would

have been necessary to start a new action for injunctive relief, in which the same testimony would have been presented. The government and the Wisconsin Dried Egg Company would be parties to both actions. As the plaintiff well states the situation,

"Both prayers for relief involve the same transaction, the same *res*, the same parties, the same court, the same evidence and the same issues, save that the amendment injected one additional issue as to the appropriateness of issuing a statutory injunction."

The issuance of an injunction is authorized under Sec. 302 (a) of the act (21 U. S. C. Sec. 322 (a)). It was believed that time and expense would be saved to all concerned by proceeding with the trial, and withholding a ruling on the motion to amend; and this was done. Claimant objected to the amendment on the ground it changed an *in rem* action to one *in personam*. It did not ask for an extension of time and, after its objection was overruled, it presented evidence on the merits.

There can be no doubt that while the seizure action was pending, a separate suit for injunctive relief could have been commenced in this court. It would then have been appropriate for the court to have ordered a consolidation. 28 U. S. C., Sec. 734; Rule 42 (a) F. R. C. P.

Where a party is before the court in an *in rem* proceeding, the court has the power to render an *in personam* judgment against him. *Hipolite Egg Co. v. United States*, 220 U. S. 45. It has likewise been held that the distinction between the proceedings *in rem* and *in personam* have no proper relation to the question of jurisdiction. *Hipolite* case, *supra*. While the court may refrain from exercising such power if by so doing it would impair substantial rights, yet where it will further the ends of justice and eliminate multiplicity of action and save expense to the parties, it should be invoked. As was well stated in the court in *Bee Mach. Co., Inc. v. Freeman*, 131 F. (2d) 190, 194:

"Allowing the amendment, then, provides in effect only a convenient short cut to a result attainable in a more round-about way. . . ."

Sec. 304 (b) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C., Sec. 334 (b)) provides:

" . . . procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty: . . ."



*U. S. v. 184 Barrels Dried Whole Eggs*

There is authority that where a claimant in admiralty has intervened in an *in rem* proceeding and filed a general appearance, the libelant may amend his libel so as to seek relief *in personam* as well as *in rem*. *The Monte A.*, 12 Fed 331. It has also been held that the avoidance of multiplicity of action by every device that is jurisdictionally possible should be one of the main objectives of the courts of admiralty. *Munson Island Lines, Inc. v. Insurance Co. of North America*, 36 F. (2d) 269.

Allowing the amendment to introduce a closely related cause of action against a resident defendant already before the court in effect merely dispensed with personal service which could have been had at any time. The amendment will be allowed.

*[Provision of Federal Act as to Adulteration]*

Proceeding now to the merits, Sec. 402 (a) of the act in question (21 U. S. C., Sec. 342 (a)) provides:

"A food shall be deemed to be adulterated— . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; . . ."

*[Plaintiff's Contentions]*

Plaintiff contends that the dried whole eggs in question did consist in part of decomposed eggs, and that whether they were fit or unfit for food is beside the point. Claimant contends that while there was a trace of fermentation and some odor (which it claims to be characteristic of such products), it denies there was any decomposition of the eggs, and contends that the food was fit for human consumption.

*[Egg Powder Not Found Injurious to Health]*

The egg powder in question, when seized, was not injurious to health when used as a food product. Two containers of egg powder were sent to the Home Economics Department of the University of Wisconsin for testing. Ordinary uncondemned egg powder was put in Container "A", while egg powder from the condemned barrels was put in container "B". Professor Personius who made the tests was not informed as to which container held the condemned powder. On opening the containers she noticed that "B" had a somewhat fishy odor. She baked a custard from each sample and obtained satisfactory results. The finished products had no unpleasant odor. She also

baked butter cakes from each sample, one batch being baked the night before she testified in court.

The cakes were cut open in court. They were satisfactory in taste and texture, and no appreciable difference in the finished bakery products could be noted. Samples of the cakes made from the condemned egg powder were eaten with no ill effects.

With permission of government officials, eleven barrels of the original seizure of 47 barrels had been shipped to Chicago. Six of these barrels had been used by bakers prior to the time the remaining five barrels were seized in Action No. 1111. Louis Nieman, whose business is wholesale bakery supplies, was the purchaser. He had many years of experience in dealing in dried egg powder, and egg albumen (dried white of egg), and over the years has imported large amounts of these products from China. He testified he was satisfied with the egg powder in question and described the odor as a characteristic cold storage odor. He paid 92c a pound for the first barrel of powder purchased and 88c a pound for the other barrels, at a time when the going price of ordinary egg powder ranged from 87c to 95c a pound. He expressed the opinion that the powder was not decomposed, and said he judged it by its smooth texture and color as well as the odor. He testified further that the longer egg powder is kept in storage, the stronger its odor becomes. He sold a 50 pound batch and also one barrel to Silverstein, a wholesale cake baker who had been in the business since 1921. Silverstein testified he considered this egg powder a satisfactory product. Mr. Fred W. Listzow, who has been a wholesaler of egg products for 32 years and who was a pioneer in the egg powder business, tasted and tested the samples of the claimant's powder which had been rejected. He testified that there was an odor to all powdered food products; that there was a slight off odor and off flavor to the powder in question; that he sent a sample of it to the largest bakery supply company in the country located at Boston; and that after that concern had tested same, it ordered a supply. Listzow could not fill the order with claimant's powder, but he did fill it with other egg powder which had been rejected by the government at Marshfield, Wisconsin, and he received no complaint as to it.



[Testimony of Government Witnesses as  
To Decomposition]

Hence, it is well established in this case that claimant's egg powder when seized by the government was not injurious to health and further that it was fit for food for human consumption. But the government argues that it rests its case on the first part of the sentence in Sec. 402 (a) (3), "If it consists in whole or in part of any filthy, putrid, or decomposed substance," ignoring the last part of the sentence, "or if it is otherwise unfit for food." Government witnesses testified as to certain scientific tests they made on the powder in question, and also as to tests previously made upon "authentic packs of dried eggs". In preparing the authentic packs, care was taken that only good quality eggs were used, and ideal sanitary conditions prevailed. The witnesses testified that under such conditions not in excess of 10 million bacteria by the microscopic count were present per gram of dried egg powder. Then other packs of good eggs were mistreated with rotten or spoiled eggs. The packs of such eggs which were dried promptly showed little if any increase in the microscopic bacterial count over known good quality eggs dried under the same conditions. However, where such mistreated eggs were permitted to stand for 18 hours in a temperature of 85°, the bacteria multiplied rapidly, in some cases exceeding one billion per gram of egg powder. The principal government witness testified that it is his conclusion that any time the microscopic bacterial count per gram of powdered eggs is in excess of 100 million, it indicates that the eggs are in part decomposed. In answer to the court's question, the witness admitted that if a million good eggs and one bad egg were mixed, he would not regard the product as decomposed, but apparently the line was arbitrarily drawn at a bacterial count of 100 million per gram. Tests of one batch of claimant's egg powder revealed a bacterial count ranging from 1,400,000 to 5,400,000,000 per gram. The bacterial count of samples from other barrels ranged from 1,200,000,000 to in excess of 10 billion.

Another government witness testified that bacteria are responsible for presence of formic, acetic, lactic, and butyric acids in egg powder, and that he made tests for these acids on the authentic packs and also on the dried egg powder under seizure and found that such acids were present in great-

er degree in the condemned powder than in the authentic packs.

[Interpretations of Section of Act Pertaining  
to Adulterated Food]

Sec. 342 (a) under which these actions were brought shows what Congress was trying to accomplish. This section has six sub-divisions:

"A food shall be deemed to be adulterated—(1) If it bears or contains any poisonous or deleterious substance which may render it *injurious to health*; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it *injurious to health*; or (2) if it bears or contains any added *poisonous* or added deleterious substance which is *unsafe* within the meaning of section 346; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise *unfit for food*; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered *injurious to health*; or (5) if it is, in whole or in part, the product of a *diseased animal* or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any *poisonous* or deleterious substance which may render the contents *injurious to health*." (Italics supplied.)

Reading the section as a whole, it is apparent Congress had in mind prohibiting the interstate commerce of food products which were dangerous to health and unfit for food.

Before the amendment of June 25, 1938, the comparable section of the act (21 U. S. C., Sec. 8) read that a food shall be deemed to be adulterated:

"Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, . . ."

The amendment inserted the word "any" before the word "filthy" and the word "otherwise" before the word "unfit", so that it read:

"A food shall be deemed to be adulterated— . . . (3) if it consists in whole or in part of *any* filthy, putrid, or decomposed substance, or if it is *otherwise* unfit for food; . . ." (Italics supplied.)

As a matter of first impression, I would conclude that the amended section indicates



*U. S. v. 184 Barrels Dried Whole Eggs*

that Congress intended that the filthy, putrid, or decomposed substance must make the product unfit for food. There would seem to be no reason for the word "otherwise" except to refer to the first part of the sentence. However, before it was amended the courts uniformly construed the act as prohibiting the interstate shipment of food which consisted in whole or in part of any filthy, putrid, or decomposed substance, irrespective of whether it was injurious to health. See: *United States v. Two Hundred Cases of Adulterated Tomato Catsup*, 211 Fed. 780, 783; *United States v. Krumm*, 269 Fed. 848, 850; *United States v. Two Hundred Cases of Canned Salmon*, 289 Fed. 157, 158; *A. O. Andersen and Co. v. United States*, 284 Fed. 542; *Knapp v. Calloway*, 52 F. (2d) 476, 477; *United States v. 133 Cases of Tomato Paste*, 22 F. Supp. 515, 516. It, of course, is assumed that Congress was aware of these interpretations and passed the amendment with these decisions in mind. *Kepner v. United States*, 195 U. S. 100; *United States v. Ryan*, 284 U. S. 167.

*[Decomposed Food Adulterated Even Though  
Fit for Food and Not Injurious]*

Bowing to this rule, I hold that the act as amended must be construed to prohibit the interstate shipment of food when it consists in whole or in part of any filthy, putrid, or decomposed substance, irrespective of whether it is fit for food or not injurious to health.

*[Question as to Proof of Decomposition]*

The remaining question is whether the government has sustained the burden of proof upon it to establish that the egg powder was decomposed. In *A. O. Andersen and Co. v. United States*, 284 Fed. 542, 544, the Ninth Circuit Court of Appeals said:

"Decomposition may begin where life ends, but meat or fish is not decomposed at that early stage. Decomposed means more than the beginning of decomposition; it means a state of decomposition, and the statute must be given a reasonable construction to carry out and effect the legislative policy or intent. . . ."

In *United States v. Commercial Creamery Co.*, 43 F. Supp. 714, 717, Judge Schwollenbach said:

"I do know that for years chemists have been seeking more efficient and rigid methods for the determination of the presence of decomposition in eggs. One need only study the reports of the Association of Official Agricultural Chemists to become aware of this effort. . . ."

*[Methods of Tests Developed in Secret]*

The tests upon which the government here relied were developed in secret. The experimenters did not disclose the methods used in their tests or their conclusions either to the Association of Official Agricultural Chemists or to any other scientific society. Furthermore, they did not announce these tests or their conclusions to the industry. They were "sprung" on the claimant herein and apparently in one other similar action tried about the same time. In view of the long efforts to try to attain some reliable standards, it would have been only fair to all concerned for such tests and conclusions to have been disclosed to the industry so that an opportunity would have been afforded to verify them, or to determine whether the arbitrary limits stated by the department were proper conclusions to be drawn from the tests. This is especially true as all decomposition and fermentation in food is not undesirable. Roquefort and other cheeses, and sauerkraut are examples.

*[Claimant's Testimony as to Practice Offsets  
Government Expert Opinion]*

The high bacteria count for the authentic pack indicated in the government tests resulted only when good eggs were contaminated and held at an 85° temperature for 18 hours or more. The evidence discloses that the claimant herein followed no such practice. It used fresh, current receipt eggs which had been inspected by candling. They were kept at an ideal temperature up to the time when they were dried. This positive testimony offsets the expert opinion of the government witness which was based upon an experiment which was never submitted to the Association of Official Agricultural Chemists or to other learned scientific societies.

*[Claimant Entitled to Judgment in All  
Three Actions]*

It is my conclusion that the government has not sustained the burden of proof to entitle it to an injunction to prevent the shipment in interstate commerce of the egg powder in Actions Nos. 852 and 853, and further that it has not sustained the burden upon it in the libel proceedings in Action No. 1111, and that the claimant is, therefore, entitled to judgment in all three actions.



UNITED STATES v. 7 JUGS, MORE OR LESS, EACH CONTAINING ONE GALLON, 14 Jugs, More or Less, Each Containing  $\frac{1}{2}$  Gallon, 20 Bottles, More or Less, Each Containing one Quart, and 20 Bottles, More or Less, Each Containing One Pint of "Dr. Salsbury's Rakos" labeled in Part "Formalin, 1.1%, Glycerite of Tannic Acid, 2.3%, Anhydrous Hydrochloric Acid, 3%, Sulphuric Acid, U. S. P. Dilute 47%, Glucose, 33.2%, \* \* \* Water, 13.4%."

UNITED STATES v. 16 CANS, MORE OR LESS, OF 50 TABLETS EACH, 51 Cans, More or Less, of 125 Tablets Each, 48 Cans, More or Less, of 300 Tablets Each, 20 Cans, More or Less, of 500 Tablets Each, and 16 Cans, More or Less, of 1000 Tablets Each of "Dr. Salsbury's Phen-O-Sal Tablets," Labeled in Part "Zinc, Calcium and Sodium Phenosulphonates; Copper Arsenite 0.34 Grains per Tablet; and Boracic Acid \* \* \* Lactose 8%."

UNITED STATES v. 67 BOTTLES, MORE OR LESS, EACH CONTAINING ONE PINT, and 60 Bottles, More or Less, Each Containing  $\frac{1}{2}$  Pint of "Dr. Salsbury's Can-Pho-Sal," Labeled in Part "Guaiacol, Beechwood Creosote, Creosote, Cresol, Oils of Eucalyptus, Camphor and Pine, Soap, Potassium Resinate \* \* \* Coumarin and Vanillin \* \* \* Water \* \* \*."

United States District Court for the District of Minnesota, Second Division.  
 Nos. 125, 126, and 127 Civil. January 31, 1944. 53 F. Supp. 746.

In construing the provisions of the Federal Food, Drug, and Cosmetic Act, consideration should be given to the purposes of the Act, its history, the specific terminology used therein, and the enforcement procedures adopted.

Title, Federal Food, Drug, and Cosmetic Act.

The purpose of the Act, to protect the public health and pocketbook, has led courts to declare with unanimity that it should be given a liberal construction in order to accomplish its remedial purposes.

Title, Federal Food, Drug, and Cosmetic Act.

In food and drug legislation, Congress has regulated what it regards as illicit articles of commerce.

Sections 304 (a), 901, Federal Food, Drug, and Cosmetic Act.

The avowed objective of the Act was to strengthen the protection afforded the public by eliminating the loopholes and expanding consumer protection.

Title, Federal Food, Drug, and Cosmetic Act.

The word "accompany" should be given an interpretation which accords with the Congressional purpose to expand the protection given consumers in redefining the concept of misbranding.

Sections 201 (m), 502 (a), Federal Food, Drug, and Cosmetic Act.

Misbranding has true significance only in terms of the consumer.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.



An article may be misbranded in commerce within the meaning of the seizure section by printed matter which, although not physically contiguous thereto, nevertheless actually did "accompany" the article for all practical purposes and in all significant aspects.

Sections 201 (m), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

In a seizure action against a poultry remedy alleging misbranding founded on false and misleading therapeutic representations, it was held that the printed matter and drugs had a common origin and common destination; that they were interlocking units of a distributional scheme the objective of which was their ultimate association and distribution together; that there was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers; and that the booklets were distributed to dealers with the intention that they would serve the purpose of labeling. The instant the product entered the channels of commerce it was to all intents and purposes as much traveling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container.

Sections 201 (m), 304 (a), Federal Food, Drug, and Cosmetic Act.

The mere fact that the products were shipped at a different time, over a different route, and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

Section 301 (k) was enacted by Congress under its authority to regulate activities affecting interstate commerce. The section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded.

Sections 201 (b), 301 (k), Federal Food, Drug, and Cosmetic Act.

In the absence of further clarification, it could not be said that the applicability of Section 301 (k) to the facts stipulated was so clear that doubt should be entertained as to the applicability of Section 304 (a).

Sections 301 (k), 304 (a), Federal Food, Drug, and Cosmetic Act.

There is nothing in the standard established in Section 502 (a) which is vague or indefinite. It prescribes a rule of conduct by which persons can measure their acts.

Sections 502 (a), 901, Federal Food, Drug, and Cosmetic Act.

What Congress has done in Section 502 (a) is to permit a claim of effectiveness to be found false or misleading where the question of effectiveness is demonstrable as a fact.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Except as affected by Section 201 (n), and the regulations issued thereunder, it is clear that food and drug legislation was intended to apply only to false or misleading expressions of fact.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The question of whether a remedy is effective is always a question of fact. The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.



**Federal Food, Drug, and Cosmetic Act**  
*U. S. v. 7 Jugs "Dr. Salsbury's Rakos"*

Before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion between schools of practitioners.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

If the evidence is such that it appears that the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and must refuse to submit the question to the jury.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

But where the evidence discloses that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Facts established by recognized scientific investigation are deserving of high standing in respect to the falsity of claims of effectiveness.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Tremendous advancements in scientific knowledge and certainty have been made since the rule in *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, was first announced. In the consideration of that rule, courts should give recognition to this advancement.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons who, the jury might find, were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

It was not improper for the court to permit experts, furnishing testimony which necessarily involved the use of their experience and training on matters of special knowledge not within the grasp of the untutored, to express opinions on the question of the effectiveness of claimant's remedies.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

There was no impropriety in instructing the jury to ignore such portion of the closing argument of claimant's counsel as attempted to impugn the Government's motives in bringing the case at that time; there was no evidence to justify the statement.

Claimant's requests to permit the jury to examine all parts of booklets in determining whether there were representations of effectiveness were properly denied, since much of the matter was wholly unrelated to the remedies involved and would have diverted the jury from the task at hand.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Since evidence as to the efficacy of the remedies had been offered by both sides throughout the trial without regard to whether it related to the prevention or treatment of disease, it was entirely proper to permit the Government to amend its pleadings to embrace both.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Blair, Curtis & Hayward and Marshall M. Holcombe of New York City, N. Y.; A. R. Eggert of Charles City, Iowa; Joseph N. Moonan and Ray G. Moonan of Waseca, Minn.; for claimant.

Victor E. Anderson, U. S. Attorney; Stanley V. Jacobson, Assistant U. S. Attorney, St. Paul, Minn.; for libelant.



## Memorandum

*[Libels Against Drugs Charged Misbranding]*

MATTHEW M. JOYCE, District Judge: These proceedings arose as a result of libels of information filed by the United States on June 1, 1942 against certain quantities of three articles of drug labeled in part "Dr. Salsbury's Rakos," "Dr. Salsbury's Phen-O-Sal," and "Dr. Salsbury's Can-Pho-Sal," charging that these articles were misbranded in violation of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. section 301, *et seq.*) and subject to seizure and condemnation. A monition was issued and the United States Marshal pursuant thereto attached the articles in the possession of Boote's Hatcheries and Packing Company, Worthington, Minnesota, hereinafter called "the Hatcheries," where they had been shipped on various dates after January 1, 1942, by Dr. Salsbury's Laboratories, Charles City, Iowa, hereinafter called "the Laboratories." Thereafter the Laboratories intervened as claimant. As a result of preliminary proceedings, amended libels were filed by the United States. Each of the amended libels charged that the three articles were misbranded in violation of Section 502 (a) as a result of the association between the articles and five printed booklets. (Government's Exhibits 1-5). These booklets, which are alleged to contain false and misleading representations concerning the effectiveness of the three articles in the treatment of specified diseases of poultry, were delivered to the Hatcheries by a sales representative of the Laboratories, and are alleged to have accompanied the articles in interstate commerce so as to constitute "labeling" as defined in Section 201 (m) (2) of the Act. Each of the libels has attached as exhibits such portions of these booklets as the government alleged were false and misleading. Answers filed by the claimant denied that the booklets constituted "labeling," denied that they contained false and misleading representations as to their effectiveness, and alleged that the three articles were not subject to seizure and condemnation under Section 304 (a) of the Act.

*[Motion To Dismiss Libels Denied]*

In order that the court might pass upon the questions of whether the booklets are "labeling" and whether the drugs are subject to seizure and condemnation, the parties stipulated the relevant facts. Claimant then moved to dismiss the libels upon the ground that the stipulation established that

the articles of drug were not misbranded "when introduced into or while in interstate commerce" as required by Section 304 (a), and, therefore, this court had no jurisdiction over the subject matter of these proceedings. On September 13, 1943, an order was made denying this motion.

*[New Trials Asked After Decrees of Condemnation]*

The three cases were consolidated for trial before a jury, and verdicts in favor of the United States were returned. The jury specially found that the three articles were misbranded. Appropriate decrees of condemnation and orders for destruction were submitted and approved. Claimant has now moved for new trials in each of the three cases and has assigned forty-five grounds of error.

*[Errors Alleged in Order Denying Motion To Dismiss]*

It is proper that consideration first be given to those specifications of error which attack the propriety of the order denying the motion to dismiss the proceedings for want of jurisdiction over the subject matter. Although the stipulation specifically applies to Civil 125, involving the product Rakos, the parties have agreed that it is also typical of and applicable to Civil 126 and 127, involving the products Phen-O-Sal and Can-Pho-Sal.

*[Facts Stipulated]*

From the stipulation it appears that the Laboratories is an Iowa corporation which distributes throughout the United States a line of poultry remedies designed for the prevention and treatment of diseases of poultry. Main offices are located at Charles City, Iowa, with branches at Columbus, Ohio, Fort Worth, Texas, and Kansas City, Missouri. Employing over 300 persons, the firm had sales in 1941 exceeding one million dollars. Distribution of its remedies is through hatcheries, drug stores, and feed and poultry houses, serviced by salesmen making regular calls.

*[Methods by Which Booklets Were Distributed]*

One such salesman is Mr. A. F. Achilles, a resident of St. Paul, whose sales territory includes Worthington, Minnesota, where the Hatcheries are located. Since his employment on January 1, 1937, Achilles has made monthly calls on dealers in his terri-



tory in the solicitation of orders and rendering poultry services. Several times yearly, printed matter is shipped to Mr. Achilles by the Laboratories for distribution to his customers. In calling upon dealers, Achilles furnished them, "according to their needs and requirements and out of a supply carried in his car," with the type of booklets here involved. "Generally, Mr. Achilles, as part of his duties, on each of his regular calls on dealers, would determine whether sufficient quantities of the said booklets were on hand, and where the supply was low, it would be replenished out of supplies carried by him. Occasionally, a dealer, in order to maintain an adequate supply, would inform Mr. Achilles of his need for the said booklets without waiting for Mr. Achilles to check the quantity on hand." Where dealers desired replenishment of their stock of booklets prior to Achilles' monthly visit, request would be made upon the Laboratories, "sometimes in connection with an order for merchandise," and a supply would either be delivered by Achilles or sent in small quantities from Charles City, Iowa. "During the spring and fall of each year as desired, a dealer would be provided by Mr. Achilles with window, counter, wall and floor display cards and posters."

It further appears from the stipulation that the quantities of the product Rakos here involved were shipped in interstate commerce from Charles City, Iowa, via railroad, on January 16 and April 11, 1942, and via truck express, on May 4, 1942, to the Hatcheries at Worthington, Minnesota. Prior to these times, the booklets here involved had been shipped and caused to be shipped in interstate commerce by the Laboratories to Achilles at St. Paul, Minnesota. These were delivered by Achilles to the Hatcheries on January 14, 1942, and April 29, 1942,

"where they were prominently displayed together with, in immediate proximity to and in association with various articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including specifically the articles of drug labeled in part 'Dr. Salsbury's Rakos' (including that quantity seized herein), 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal', and were available for reading and accessible for distribution with the sale, actual or potential, of these articles of drugs. The posters and display cards of the type herewith submitted as Exhibits A through E, which had been delivered by Mr. Achilles prior to the dates specified herein, were similarly displayed."

It is also stated that in addition to being displayed and available with the drugs, the booklets "are distributed by dealers . . . in over the counter transactions with purchases of one or more of the articles of drugs manufactured and sold by Dr. Salsbury's Laboratories including the articles of drug labeled in part, 'Dr. Salsbury's Rakos,' 'Dr. Salsbury's Phen-O-Sal', and 'Dr. Salsbury's Can-Pho-Sal'. Also, a store patron may freely avail himself of one or more of the said booklets even though making no purchase". It is also agreed that the principal distribution of Government's Exhibit 5, several million annually, is by direct mailing to farmers throughout the United States at the request of dealers. These are mailed from Mount Morris, Illinois, where they are printed.

*[Pertinent Provisions of Federal Food, Drug, and Cosmetic Act]*

The following provisions of the Act are pertinent to claimant's contention. Section 502 (a), defines misbranding as follows: "A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular." "Labeling" is defined by section 201 (m) (2) to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article". So far as applicable, Section 304 (a) provides that "Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . ."

*[Claimant Contends Drugs Not Misbranded When in Commerce]*

The specific contention made by claimant is that the stipulation establishes that while the quantities of Rakos here involved were shipped on January 16, April 11, and May 4, 1942, the booklets had been shipped to Achilles prior thereto, and were delivered to the Hatcheries on January 14, and April 29, 1942. Therefore, there is said to be a complete lack of identity as to times of shipment, times of arrival and routes traveled between the drugs and the booklets. Accordingly, it is argued, the drugs were not misbranded "when introduced into or while in interstate commerce" as required by Section 304 (a).



*U. S. v. 7 Jugs "Dr. Salsbury's Rakos"**[Food and Drug Legislation To Be Given Liberal Construction]*

In passing upon this contention, of paramount importance is the fact that the Federal Food, Drug & Cosmetic Act is an enactment under the Commerce Clause. Accordingly, in construing its provisions, consideration should be given to the purposes of the Act, its history, the specific terminology used therein and the enforcement procedures adopted. *Kirschbaum v. Walling*, 316 U. S. 517, 520. The history behind the present Act dates from 1906 when the Food and Drugs Act was adopted. 21 U. S. C., Sec. 1, *et seq.* One of the most important enactments under the Commerce Clause, its purpose of protecting the public health and pocketbook against adulterated and misbranded foods and drugs, has led courts to declare with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes. *United States v. 95 Barrels of Vinegar*, 265 U. S. 438; *United States v. Antikammia Chemical Co.*, 231 U. S. 654, 655; *United States v. Schider*, 246 U. S. 519, 522; *Wm. M. Galt Co. v. United States*, (1913) 39 App. D. C. 470; *United States v. Research Commercial Creamery Co.*, (D. C. Wash. 1942) 43 F. Supp. 714, 715.

*[Construction of 1906 Act]*

Stating the basis for the enactment of the 1906 Act, the Court in *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, said: "The statute rests, of course, upon the power of Congress to regulate interstate commerce; and, defining that power, we have said that no trade can be carried on between the states to which it does not extend, and have further said that it is complete in itself, subject to no limitations except those found in the Constitution." That Congress was regulating what it regarded as illicit articles of commerce was made equally clear: "We are dealing, it must be remembered, with illicit articles,—articles which the law seeks to keep out of commerce because they are debased by adulteration, and which punishes them (if we may so express ourselves) and the shipper of them." 220 U. S. 57. In the case of adulterated articles, this illicit quality was supplied by the presence of a deleterious substance in the article (*Hipolite Egg Co. v. United States*, *supra*) and in the case of misbranding, it was supplied by the presence of a false label on the article. *McDermott v. Wisconsin*, 228 U. S. 115, 131-133. "The object of the statute is to prevent the misuse of the facilities of

interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food". 228 U. S. 131. The remedy of seizure and condemnation was said to be an appropriate means for preventing the transportation of such articles. *Hipolite Egg Co. v. United States*, 220 U.S. 57-58.

Inasmuch as Congress was dealing with what it regarded as illicit articles of commerce, it is not surprising that under the 1906 Act, the concept of misbranding was limited to the label or brand appearing upon the articles or package. Accordingly, under Section 8 of the 1906 Act, an article was misbranded if "the *package or label* . . . shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular". (Emphasis supplied). Any article so labeled was illicit in commerce. "The label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress". *McDermott v. Wisconsin*, 228 U. S. 133.

*[Concept of Misbranding Enlarged by 1912 Amendment]*

It soon became apparent, however, that this concept of misbranding was too narrow. Thus a manufacturer could make false claims on a circular enclosed in the package containing the article without misbranding it under the phraseology of Section 8. *United States v. American Druggists' Syndicate*, (C. C. N. Y. 1911) 186 Fed. 387; *United States v. Newton Tea & Spice Co.*, (D. C. Ohio 1920) 275 Fed. 394. Congress in 1912 endeavored to correct this deficiency by passing the Sherley Amendment which defined as misbranded any article whose "package or label shall *bear or contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein which is false and fraudulent". (Emphasis supplied.) 21 U. S. C., Sec. 10 Third. The attack upon the constitutionality of this amendment was considered in *Seven Cases v. United States*, 239 U. S. 510. The Supreme Court decided that circulars bearing false and fraudulent therapeutic claims enclosed within the package containing the article would now misbrand it. Just as the label, under the 1906 Act, conferred upon the article its illicit character in commerce, so now the circular under the 1912 amendment



provided this status. "The false and fraudulent statement . . . in the package . . . gives to the article its character in interstate commerce." 239 U. S. 517.

*[Concept of Misbranding Further Expanded in 1938 Act]*

So prior to 1938, the law protected the public only where false claims were made on the label or package or in a circular within the package. Accordingly, to avoid the jurisdiction of the Food and Drug Administration, a patent medicine manufacturer needed only to separate physically the printed matter bearing the false claims from the article itself. This and other deficiencies in the old Act resulted in its complete overhauling by Congress and culminated in the enactment in 1938 of the present Act. The avowed objective of the new Act was to strengthen the protection afforded the public by eliminating the loopholes and expanding consumer protection. Cong. Rec. 73rd Cong. 2nd session, Vol. 78, Part 5, pp. 4567-4573. Many new provisions were added and old ones enlarged. The concept of misbranding was expanded to include any drug whose "labeling" is false or misleading. "Labeling" comprehends labels, container wrappers, and all written, printed and graphic matter which accompanies any article of food or drug. Enforcement procedures were expanded by the inclusion of new prohibited acts and injunctive relief. (See Section 301, 303). The seizure and condemnation provisions were modified to eliminate obstacles to effectiveness and their availability was enlarged. (Compare Section 10, 1906 Act, with Section 304 (a), 1938 Act).

*[Interrelation of Sections 201 (m) (2), 502 (a) and 304 (a)]*

It is perfectly clear that to resolve the present controversy it is necessary to consider the interrelation of Sections 201 (m) (2) defining labeling, 502 (a) defining misbranding, and 304 (a) providing for seizure and condemnation. Unless an article of drug is misbranded when it enters or while in interstate commerce, seizure is unavailable. There is no misbranding unless its labeling is false or misleading. Printed matter is labeling and will misbrand if it appears on the article, in the package or accompanies the article and is false or misleading in any particular.

*[Word "Accompany" Intended To Have Broad Coverage]*

Realizing that Congress was attempting to expand the protection given consumers in redefining the concept of misbranding, it is evident that the word "accompany" should be given an interpretation which accords with the Congressional purpose. There is evidence in the legislative history of the labeling section indicating that broad coverage was intended. Thus in addressing the Senate committee in regard to this section, W. G. Campbell, Commissioner of the Food and Drug Administration, stated: "The term 'labeling' is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug or cosmetic. . . ." United States Senate Report 1944, 73rd Cong. 2nd Session, p. 16. There is nothing elsewhere in the history which in any way indicated that anything less than that was intended.

The narrow question here is the extent to which printed matter must "accompany" articles of drug at the time of introduction into or while in interstate commerce in order that such articles can be said to be "misbranded" within the meaning of Section 304 (a). In answer to this question, the government states that the old physical contiguity test of misbranding, operative under the old law, has been discarded and the present Act should be given the broadest possible interpretation in accomplishing the consumer protection intended by Congress. Claimant states that it does not believe that physical annexation between the drug and printed matter is always necessary, but insists that because there are differences in times of shipment, times of delivery and routes traveled, the drugs here seized could not possibly have been "misbranded" at any time in their interstate journey.

*[Full Scope of Present Concept of Misbranding Applied in Interpreting Section 304 (a)]*

The provision in Section 304 (a) that an article to be subject to seizure must have been "misbranded" during its interstate journey is the counterpart in the present Act of the theory and terminology of Section 10 of the old Act (21 U. S. C. Sec. 14). Thereunder, seizure was available as to any "article of . . . drug . . . that is . . . mis-



*U. S. v. 7 Jugs "Dr. Salsbury's Rakos"*

branded . . . and is being transported from one state . . . to another . . ." Since the concept of misbranding was then limited to printed matter physically contiguous with the article, necessarily there was an actual physical misbranding throughout the interstate journey. However, as we have seen, the concept of misbranding has now been extended by Congress beyond this restricted notion of physical contiguity. Since Congress should not be thought to have expanded the substance without expanding the remedy, in asking whether an article is "misbranded" in commerce as required by Section 304 (a), we must necessarily apply the enlarged concept which the law has now created. The full scope of the present concept of misbranding must be applied in the interpretation of Section 304 (a). As we have seen, Congress was dealing in this legislation with articles which were regarded as illicit. Accordingly, just as it was the label in 1906 and the circular in 1912 which conferred upon an article its misbranded status in commerce, so now under the present Act, printed matter which can be said to have accompanied an article confers its misbranded status in commerce.

Aside from the theory of the food and drug legislation, it is manifest that misbranding has true significance only in terms of the consumer. It matters little whether a farmer goes to Boote's Hatcheries and sees a large display card proclaiming the benefits of Rakos in the treatment of coccidiosis, or finds the same matter actually upon the carton or label of the product. If such representations are false, he is as much defrauded irrespective of the location of the printed statement. Nor does it matter to the farmer whether the booklets were physically side by side with bottles of Rakos during the interstate journey, or were delivered by a salesman. When the farmer enters a dealer's store, he finds the Rakos and the booklets together in one indivisible merchandising unit. Nothing on the bottle of Rakos, or on or in the carton in which it is sold tells the farmer that Rakos shall be used in the treatment of coccidiosis. The only statements to that effect are found in booklets displayed and distributed with Rakos and upon placards and wall posters prominently arranged in the store. The fact that the farmer has suffered an out-of-pocket loss by relying upon these representations should not be obscured by any subtle inquiries, concerning whether the printed representations rode with the drugs

on the same train, at the same time or over the same route.

*[Drugs Misbranded Because Booklets Accompanied Drugs in Commerce]*

In support of its claim that seizure and condemnation are available here, the Government has made three contentions. First, it claims that if printed matter at any time after an interstate shipment of drugs comes into a relationship which complies with the requirements of "labeling", the misbranding which then occurs is retroactively effective from the moment the drugs entered the channels of commerce. Although the use by the drugs of the facilities of commerce seemingly is proper, yet the end result was the misbranding which Congress sought to avoid, and this wrong was a wrong *ab initio*. Second, the Government contends that the stipulation establishes that the drugs were "misbranded" in commerce because the facts show that the booklets did actually accompany the drugs in commerce. Third, the Government contends that the booklets and drugs were part of one interstate transaction, and that "commerce among the states is not a technical legal conception, but a practical one, drawn from the course of business." *Swift & Co. v. United States*, 196 U. S. 375, 398. Since I concur in the correctness of the second contention, it is unnecessary to consider either of the other arguments.

*[Physical Accompaniment Throughout Interstate Movement Not Essential]*

In essence the question is: Must there be physical accompaniment throughout the entire interstate movement of the drugs in order for seizure and condemnation to be available? The question is answered in the negative. So to hold would be to resurrect the physical proximity theory of misbranding. May not an article be "misbranded" in commerce within the meaning of Section 304 (a) by printed matter which, though not physically contiguous thereto, nevertheless actually did "accompany" the article for all practical purposes and in all significant aspects? This question is answered in the affirmative.

*[Other Pertinent Cases]*

The answer to these questions was first made in *United States v. Research Laboratories*, (C. C. A. 9, 1942) 126 F. (2d) 42, where the libel, which the lower court dismissed, alleged that the circulars accompan-



ied the articles in commerce by having the same origin and in simultaneously arriving with the articles at destination where they were placed in the same room in the consignee's warehouse. In reversing the lower court, the court said: "The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. *Clearly, therefore, they accompanied each other regardless of whether, physically, they were together or apart during their journey.*" (Emphasis supplied). The principle of that case in rejecting the concept of physical contiguity as a test for misbranding under Section 304 (a), in my opinion is sound. Once this principle is comprehended, it is simply a question of determining in a given case whether the relationship between the article and the printed matter is sufficiently proximate to fulfill the requirement of accompaniment.

The word "accompany" as used in Section 201 (m) (2) was said in *United States v. Lee*, (C. C. A. 7, 1942) 131 F. (2d) 464, 466, to mean: "The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with,' Webster's New International Dictionary, 2d Ed." Naturally, meanings of accompany will vary in connection with subject matter. "Accompany" as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there "can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates" (*United States v. Lee*, at p. 466), the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products Rakos, Phen-O-Sal and Can-Pho-Sal have none.

*[Both Drugs and Booklets Used Interstate Commerce To Defraud]*

The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a

distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. The instant that the product Rakos entered the channels of commerce enroute to the Hatcheries, it was to all intents and purposes as much travelling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container. It is unquestionable that both the drugs and the booklets used the facilities of interstate commerce to accomplish a defrauding of the public. For this transgression, the products are subject to seizure and condemnation.

*[Absence of Physical Association During Interstate Journey Immaterial]*

Were not the factors just stated to be given primary consideration, there would be a multiplication of refinements. Starting with the case of a circular in the package or in the shipping carton containing the drug, there would be a question as to circulars in a different car on the same train, or a different train, at a different time, over a different route, or by a different type of carrier. The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.



## [Applicability of Section 301 (k)]

Claimant insists, however, that there is no occasion for employing seizure and condemnation in this situation, as the Government has a right to proceed by injunction under Section 301 (k).<sup>1</sup> Claimant states that this section authorizes the Government to enjoin the Laboratories from causing an association between the printed matter and the drugs at the retailer's place of business. *United States v. Lee, supra.* The Government, however, does not concede that this section is necessarily available here and suggests several arguments which claimant might have made as to the non-applicability of Section 301 (k) had the Government attempted to use it.

This court does not in this proceeding propose to mark out the limits of Section 301 (k). Seemingly, however, it was enacted by Congress under its authority to regulate activities affecting interstate commerce. See *Labor Board v. Jones & Laughlin*, 301 U. S. 1. In referring to alteration, mutilation, destruction, obliteration or removal of labels this section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded. In the instant case, drugs and booklets were flowing through commerce in a relationship which has been found to make illegal the use by the drugs of the facilities of commerce. In any event, in absence of further clarification, it cannot be said that the applicability of Section 301 (k) to the facts set forth in the stipulation is so clear that doubts should be entertained as to the applicability of Section 304 (a).

## [Error Asserted in Failure To Grant Requested Instructions]

The ground of error most vigorously asserted by claimant in its motion goes to the failure of the court to grant certain requested instructions. Requests 3 and 4 were as follows:

"The law under which this proceeding is instituted does not contemplate that statements with reference to the curative or therapeutic value of the drug shall be deemed false or misleading with respect to matters as to which there is an honest

difference of opinions between schools and practitioners."

"In the treatment of diseases of animals honest differences of opinion may arise between schools and practitioners as to the therapeutic or curative value of drugs. Statements with references to the curative value of drugs or helpfulness in assisting in bringing about a cure are not to be deemed false and misleading merely because differences of opinion exist between different groups of Veterinarians, or different groups skilled in this particular line of endeavor as to the curative value."

Failure to grant these requests is said to have constituted unconstitutional application of Section 502 (a), for the reason that it permitted the jury to find claims of effectiveness to be false and misleading upon the basis of differences of expert opinion. Failure to charge as requested is said to have permitted the jury to weigh differences of expert opinion and to decide whether the claims of effectiveness made by claimant were false or misleading depending upon whether it followed the experts for the Government or those for claimant. This, it is said, introduced such uncertainty into Section 502 (a) as would make it void for uncertainty. Cases cited in support thereof are *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94; *United States v. Johnson*, 221 U. S. 488; *Seven Cases v. United States*, 239 U. S. 510; and cases holding that a statute must define an offence with reasonable certainty in order that a person may know what is prohibited. *United States v. Cohen Grocery Co.*, 255 U. S. 81; *Connally v. General Const. Co.*, 269 U. S. 385.

## [Section 502 (a) Not Void for Indefiniteness and Uncertainty]

The law under which these proceedings were instituted provides that a drug is misbranded if its labeling is false or misleading in any particular. There is nothing in this standard which is vague or indefinite. It prescribes a rule of conduct by which persons can measure their acts. In and of itself there is and can be no contention that the provisions of Section 502 (a) are void for indefiniteness and uncertainty. *United States v. Cohen Grocery Co., supra*; *Connally v. General Const. Co., supra*; *Coplin v. U. S.* (C. C. A. 9, 1937), 88 F. (2d) 652, 657.

<sup>1</sup> The full text of Sec. 301 (k) is as follows: "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or

cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."



[Whether Question of Effectiveness Is  
Opinion or Fact Depends on Evidence]

Claimant, however, supports its contention that the standard is uncertain and indefinite by adding another element,—the difference of opinion between the experts appearing for the Government and those appearing for claimant. It is said that the question of "whether or not these remedies are of value in the treatment of poultry diseases involves a question of opinion and not a strict question of fact". Therefore, it is concluded, refusal to charge the jury as requested in 3 and 4 placed an unconstitutional interpretation upon Sec. 502 (a) by allowing the jury to find the claims of effectiveness false or misleading by deciding between two groups expressing different opinions about the effectiveness of these remedies.

Implicitly, the argument for claimant proceeds upon the assumption that it would be beyond the power of Congress to permit a claim of effectiveness to be found false by a jury where medical or veterinary opinion is divided on the matter. Whatever the merit of this assumption, it is clear that Congress has not attempted to do this in Section 502 (a), nor did it do so in prior legislation. What Congress has done is to permit a claim of effectiveness to be found false or misleading where the question of effectiveness is demonstrable as a fact. I do not think that I have permitted more in these proceedings.

The law in regard to the effect of a difference of medical opinion upon a proceeding in which a claim of effectiveness is sought to be proved false stems from *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94. In that case, the Postmaster General upon the basis of evidence satisfactory to him, issued a fraud order upon the ground that the Magnetic Healing School was using the mails to obtain money by means of false and fraudulent pretenses. An injunction was sought to restrain the Postmaster from carrying out the terms of the fraud order. A demurrer to the bill was sustained in the lower court and reversed on appeal. Laying constitutional consideration to one side, the Supreme Court held that the School's claims of effectiveness for its method of treatment of diseases, as to which there was a difference of medical opinion, could not be condemned as false for the reason that, being based upon differences of opinion, there was no standard of

fact or truth by which to measure the falsity of the claims. The court stated that efficacy of treatment was a matter of opinion entirely and not a matter of absolute fact capable of proof as a fact. Under the statute, the Postmaster General was said to have no authority to decide between the conflicting opinions. The court held that where variant opinions appear as to claims of effectiveness, such a statute does not apply as a matter of law.

Later cases made the *McAnnulty* rule applicable to food and drug legislation under which statements constituted misbranding where false or misleading in any particular (1906 Act), or false and fraudulent (1912 Amendment), as applied to curative claims. *United States v. Johnson*, 221 U. S. 488; *Seven Cases v. United States*, 239 U. S. 510. Although the majority of the court in the *Johnson* case believed that Section 8 of the 1906 Act in declaring as misbranded statements which were false or misleading applied only to statements of strength, identity, quality and purity and did not apply to claims of curative value, and intimated that Congress was unlikely to distort its constitutional power to establish criteria in regions where opinion is wide apart, yet it is significant that the decision does not rest upon a constitutional basis. It was simply decided that Section 8 was not intended to apply to expressions of curative value. Following this decision, Congress amended the 1906 Act expressly to provide that statements of curative value would constitute misbranding if "false and fraudulent". When the constitutionality of this amendment was attacked upon the same ground as claimant advances here, a unanimous court in *Seven Cases v. United States* held that the amendment was intended to apply not to expressions of opinion but only to expressions of effectiveness which were plainly contrary to fact.

Although the court in the *McAnnulty* case had said that assertions of effectiveness were always matters of opinion because "There is no exact standard of absolute truth by which to prove the assertion false and a fraud . . . [since] . . . the claim . . . cannot be the subject of proof as of an ordinary fact", 187 U. S. 104, the court now states that there is a category of assertions which fall outside the field of opinion and into the field of fact. "Congress deliberately excluded the field where there are honest differences of opinion between



schools and practitioners . . . Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion, but constitute absolute falsehoods". *Seven Cases v. United States*, 239 U. S. 517. In view of the fact that Justice Hughes, who spoke for a unanimous court in *Seven Cases v. United States*, dissented from the majority opinion in the *Johnson* case as to the scope of Section 8 of the 1906 Act, the language which he used in his dissent is of significance upon this question. He stated, "It is, of course, true, that when Congress used the words 'false or misleading statement,' it referred to a well defined category in the law, and must be taken to have intended statements of *fact*, and not mere expressions of opinion. . . . But, granting the widest domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative properties are downright falsehoods and in no sense expressions of judgment. This field I believe this statute covers." 221 U. S. 504. In using this language, Justice Hughes was referring to terminology in the 1906 Act which is in all respects identical with that contained in Section 502 (a).

Plainly, therefore, the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion. See House Committee Report No. 2139, 75th Congress, 3d Session. Except as affected by Section 201 (n) and the regulations issued thereunder, it is clear that food and drug legislation was intended to apply only to false or misleading expressions of fact. It seems manifest that the question of whether a remedy is effective is always a question of fact. A remedy cannot be both effective and ineffective under identical circumstances. The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading within the meaning of Section 502 (a). Necessarily, therefore, whether in a given case the question of effectiveness is one of opinion or fact depends entirely upon the evidence which is introduced.

Under the law as it now exists, before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion be-

tween schools or practitioners. As stated by Justice Hughes in his dissent in the *Johnson* case, "I entirely agree that in any case brought under the act for misbranding,—by a false or misleading statement as to curative properties of an article,—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false." 221 U. S. 507. If the evidence is such that it appears that the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. *American School of Magnetic Healing v. McAnnulty*, *supra*; see *L. B. Silver v. Federal Trade Commission*, (C. C. A. 6, 1923), 289 Fed. 985; cf. *Bruce v. United States*, (C. C. A. 9, 1912) 202 Fed. 98. But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. What the evidence shows in a given case is a question of law for the court to decide.

[*Interpretation of Section 502 (a) Not Unconstitutional*]

In light of these considerations, it appears that the claims of unconstitutionality made by claimant as to the interpretation given to Section 502 (a) in the charge are not well taken. The only situation where claimant could possibly say that its claimed constitutional rights had been invaded would be where a court had permitted the jury to find a claim of effectiveness false on the basis of evidence which indicated only a contrariety of opinion. No possible question of constitutionality can arise in a case where the evidence upon which the question of effectiveness was decided by the jury has the necessary factual basis. Such factual proof was present at the time these cases were submitted to the jury.

[*Evidence Showed Remedies Worthless*]

Scientific witnesses for the Government in this case made elaborate and comprehensive tests of claimant's remedies under conditions most favorable to the remedies.



Practically all of the experts testifying for the Government had conducted significant experimentation either in the field or in the laboratory. In the experimentation, all factors were controlled and a complete identity of circumstances and environment for the experimental poultry was provided. The report of such tests showed conclusively that the remedies were absolutely worthless and without any benefit whatsoever. The infected, untreated experimental group showed the same rate of mortality and recovery as the infected, treated group. These tests were duplicated and corroborated away from the laboratory under so-called field conditions. These tests were recognized by outstanding men of science as constituting conclusive evidence by recognized scientific standards that the remedies were wholly ineffective.

*[Advancements in Scientific Knowledge and Certainty]*

Facts established by recognized scientific investigation are deserving of high standing in respect to the falsity of claims of effectiveness. *Elliott Works v. Frisk*, (D. C. Iowa 1932) 58 F. (2d) 820, 824-825; cf. *United States v. Lesser*, (C. C. A. 2, 1933) 66 F. (2d) 612, 616. Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the *McAnnulty* case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the *McAnnulty* rule, courts should give recognition to this advancement.

*[Claimant's Experimental Data and Expert Witnesses Lacking in Significance]*

None of the experimental data introduced by claimant in any way directly or completely opposed the conclusiveness of the experimentation conducted by Government experts, and the jury was entitled to find that it was lacking in significance. It is true that claimant produced veterinarians from its own organization and from other remedy companies who expressed the opinion that these remedies were effective. But it is unthinkable that this expression of opinion by these so-called experts could in any way operate to prevent these cases from being submitted to the jury or to require the court to instruct the jury to ignore all expressions of opinion on the part of both sides.

*[Issue of Misbranding and Effectiveness Decided by Jury on All Testimony]*

But the requested instruction did not in any way raise these issues. The requests did not ask the court to instruct the jury to ignore all opinion testimony. As the summation by claimant's counsel indicated, claimant was perfectly willing that the jury should have the benefit of the opinions rendered by its experts that these remedies were effective. Accordingly, the jury was instructed that the issue of misbranding, i. e. the question of effectiveness, should be decided upon a consideration of all the testimony. Certainly where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct opposition to established scientific fact.

*[Instructions Refused Because of Abundant Evidence of Ineffectiveness]*

The only possible question, which claimant's requests raised was whether there was in the evidence any more than mere difference of opinion between groups of veterinarians. Since there was abundant factual evidence of ineffectiveness, the requests served no purpose and were therefore refused. Certainly there was no occasion for telling the jury about what the rule would have been had the evidence been different than it was.

*[Failure To Give Other Instructions Assigned as Error]*

Failure to give other requested instructions is also assigned as error. These asked that the jury be told that the booklets did not represent that the remedies would cure, but merely indicated that the remedies would be helpful. Also, requests were made as to what degree of helpfulness a drug must have in order that it possess therapeutic or curative properties.

*[Unnecessary To Tell Jury What Would Be Necessary for Remedies To Be Curative]*

The libels in this case charged that the representations contained in the booklets were false and misleading because they represented that the remedies were effec-



*U. S. v. 7 Jugs "Dr. Salsbury's Rakos"*

tive in the treatment of poultry diseases when they were not effective. Whether they were represented to be effective and whether they were effective were the issues in the case. The testimony for the Government, acquiesced in by three witnesses for claimant, was that before these remedies could be effective, a capacity to destroy or inhibit germs was necessary. Under this state of the evidence, it was unnecessary to tell the jury about what would be necessary for the remedies to be curative or therapeutic. Whether the statements appearing in the booklets represented the remedies to be effective was for the jury to say in light of the ordinary meaning of the language used. *Bradley v. United States*, (C. C. A. 5, 1920) 264 Fed. 79; *Hall v. United States*, (C. C. A. 5, 1920) 267 Fed. 795; *United States v. John J. Fulton Co.*, (C. C. A. 9, 1929) 33 F. (2d) 506.

*[Receipt of Opinion Evidence Not In Error]*

Claimant assigns as error the action of the court in permitting the experts for the Government to testify as to the ultimate issues in the case, citing *United States v. Spaulding*, 293 U. S. 498. All of the opinion evidence given by the Government's experts necessarily involved the use of their experience and training on matters of special knowledge not within the grasp of the untutored. Clearly, it would seem not improper for the court to permit them to express opinions upon the question of the effectiveness of claimant's remedies. *Dr. J. H. McLean Medicine Co. v. United States*, (C. C. A. 8, 1918) 253 Fed. 694; *Eleven Gross Packages v. United States*, (C. C. A. 3, 1916) 233 Fed. 71; *Kar-Ru Chemical Co. v. United States*, (C. C. A. 9, 1920) 264 Fed. 921; *United States v. Chichester Chemical Co.*, (App. D. C. 1924) 298 Fed. 829. All opinions given by the experts who testified for the Government were directly or indirectly expressed in relation to this question of effectiveness and did not invade the function of the jury. Moreover, in the examination of its experts, claimant was allowed similar latitude. In fact, in an effort to permit claimant to present to the jury everything which could possibly be of benefit in support of its claims of effectiveness, the court allowed very great latitude in the receipt of evidence, even to the point where opinion evidence from lay persons was received. Accordingly, if any error was committed, it was in claimant's favor and it is now in no position to complain.

*[No Evidence To Justify Impugning Government's Motives]*

Other claims of error may be summarily dismissed. I see no impropriety in instructing the jury to ignore such portions of the closing argument of claimant's counsel as attempted to impugn the Government's motives in bringing this case at the present time. There was no evidence to justify this statement. See *London Guarantee & Accident Co. v. Woefle*, (C. C. A. 8, 1936) 83 F. (2d) 325, 338-344. The claimed impropriety in the argument of Government counsel, if it existed, was prompted by the improper argument of opposing counsel and was not open to censure. *Chicago & N. W. Ry. Co. v. Kelly*, (C. C. A. 8, 1934) 74 F. (2d) 31; *Union Electric Light & Power Co. v. Snyder Estate Co.*, (C. C. A. 8, 1933) 65 F. (2d) 297, 301-302.

*[Examination of Unrelated Parts of Booklets Properly Denied]*

I feel that claimant's requests to permit the jury to examine all parts of the booklets in determining whether there were representations of effectiveness was properly denied. Much of this matter was wholly unrelated to the remedies involved and would have diverted the jury from the task at hand. Request No. 18, submitted by claimant, was granted and this in my opinion was all that it was entitled to.

*[Amendment of Government's Pleadings Proper]*

Throughout the trial, evidence as to the efficacy of the remedies was offered by both sides without regard to whether it related to prevention or treatment of disease. It was, therefore, entirely proper to permit the Government to amend its pleadings to embrace both. Rule 15 (b) of the Federal Rules expressly sanctions this.

*[Harmless Error in Exclusion of Impeachment Evidence]*

Any error in the exclusion of Exhibit P was harmless. The materiality of and foundation for this exhibit were not clearly shown. But that aside, it was offered as impeachment evidence only. In view of the admission of Exhibit Q, its only effect would have been cumulative.



**UNITED STATES v. 2 BAGS, MORE OR LESS, EACH  
CONTAINING 110 POUNDS POPPY SEEDS**

United States District Court for the Northern District of Ohio, Eastern Division. Civil Action No. 21092. Filed February 3, 1944. 54 F. Supp. 706.

Reversed, 147 F. 2d 123. See page 135.

Claimant shipped to jobbers, in bags truthfully labeled, white poppy seeds which had been colored to resemble more expensive poppy seeds. If questions as to whether the product was adulterated under Section 402 (b) (3) and (4) were answered with reference to retailers and consumers, they would have to be answered in the affirmative, since retailers and consumers would be likely to be deceived; but if answered with reference to jobbers, they should be answered in the negative, since jobbers were well aware of the distinctions between the seeds.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

The libel was dismissed, since the court held that the legality of the product must be tested by its condition at the time of seizure and not by what its condition might be after it had passed beyond interstate commerce channels, or had been transposed from the packages in which it was shipped, or had been changed in form or content.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

Federal authorities cannot construe the Act as forbidding the shipment of goods properly labeled merely because they may be subsequently sold without proper label or designation.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

If an interstate shipment is not a "palming off" of something inferior, it is not in violation of the statute merely because it has a potentiality of deception.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

Don C. Miller, U. S. Attorney, F. B. Kavanagh, Assistant U. S. Attorney, for plaintiff.

George N. Levine, Brooklyn, N. Y., Marc J. Grossman, Cleveland, Ohio, for defendant.

[*Facts of Case*]

WILKIN, District Judge: This is a civil action in which plaintiff seeks judgment that certain bags of poppy seeds shipped by Arco Products Company in interstate commerce be seized and confiscated.<sup>1</sup> The gravamen of the complaint is that the seeds were adulterated within the meaning of Section 342 (b) (3) and Section 342 (b) (4) of Title 21 U. S. Code. The defendant contends that there is no basis for the complaint in fact or law. In last analysis the issue turns upon a point of law.

The undisputed or established facts are that the defendant shipped to jobbers in other states white poppy seeds known as British India seeds which had been colored by charcoal pigment made from burned poppy seeds. A short time after this coun-

try's involvement in the present war, Dutch Blue and Turkish poppy seeds went off the market. Those seeds have a natural blue or dark grey color and had been used extensively, almost exclusively, for decorative and flavoring purposes in the manufacture of bread, rolls, and other baked goods. When the only available poppy seed on the market was the British India white seed, the defendant devised a method of coloring it for "eye appeal". There was a marked difference between the price of Dutch Blue and Turkish seeds, on the one hand, and the British India seeds, on the other. The dark seeds sold for 65 to 90 cents a pound, while the white seeds sold for 10 to 11 cents a pound. The white seeds after being colored sold for 22½ cents a pound. The seeds were shipped in bags labeled "Pro-

<sup>1</sup> By agreement of parties the decision in this case is to be determinative of similar complaints filed in Scranton, Pennsylvania, namely, Civil

No. 914, and in St. Louis, Missouri, Civil No. 2005.



duce of British India. Artificially colored with vegetable colors." In the bills sent to jobbers the goods shipped were referred to as "White poppy seed from British India, artificially colored."

[Questions Raised]

Counsel for plaintiff, at the beginning of the argument, in their brief, say:

"The question now arises on all of the testimony as to:

I. WHETHER THE ARTICLE IS ADULTERATED WITHIN THE MEANING OF SECTION 342 (b) (3), TITLE 21, U. S. C., IN THAT *INFERIORITY HAS BEEN CONCEALED BY ADDITION OF SUBSTANCE, CHARCOAL.*

II. WHETHER THE ARTICLE IS ADULTERATED WITHIN THE MEANING OF SECTION 342 (b) (4), TITLE 21 U. S. C. IN THAT SUBSTANCE, CHARCOAL, HAS BEEN ADDED THERETO SO AS TO MAKE IT APPEAR BETTER OR OF GREATER VALUE THAN IT IS."

If those questions are answered with reference to retailers and consumers they would have to be answered in the affirmative. If however, they are answered with reference to jobbers, the evidence convinces the court that they should have a negative answer. In spite of the fact that the British India seeds on close examination reveal a smaller size and a more uniformly black or very dark grey shade and that Dutch Blue and Turkish seeds are somewhat larger and contain variegated shades of color, still a cursory look at the seeds would reveal no difference. Any one inexperienced in such matters would fail to note the difference between the naturally dark seeds and the artificially colored seeds. While the difference in flavor, if any, is slight and there is no difference in food value, there is nevertheless a difference in commercial value or price, and the coloring of the white seeds does conceal that price inferiority and does make the white seeds appear better or of greater value, than they are. The court is satisfied from the evidence that jobbers are well aware of the distinctions and would not be deceived by the artificial coloring, especially when they are sold under a label informing the purchaser that they are the product of British India, artificially colored. The difference in price would also be a well understood notice to jobbers that the seeds sold were not Dutch Blue or Turkish.

[*Legality of Product Tested by Condition at Time of Seizure*]

In view of these facts the legal issue arises whether the questions are to be answered with reference to the retailer and consumer or whether merely as to the consignee in the interstate sale. In view of the holding in a long line of decisions, the legality of the product must be tested by its condition at the time of seizure and not by what its condition might be after it has passed beyond interstate commerce channels or been transposed from the packages in which it was shipped or changed in form or content. *U. S. v. 492 cases, more or less, Orange Juice, etc.*, 20 F. Supp. 520; *U. S. v. Great Atlantic & Pacific Tea Co.*, 92 F. (2d) 610 (syl. 3, 4, p. 611); *Austin v. Tennessee*, 179 U. S. 343; *Sonneborn Bros. v. Cureton*, 262 U. S. 506; *Schechter Corp. v. U. S.*, 295 U. S. 495, (syl. 3, 4).

[*Purpose of Coloring To Make Product More Pleasing to Eye*]

It seems to this court that this case falls within the principles announced in *U. S. v. 492 cases Orange Juice, supra*, *U. S. v. Nesbitt Fruit Products*, 96 F. (2d) 972, and in *U. S. v. Lexington Mill & Elevator Co.*, 232 U. S. 399. In the latter case the Supreme Court held that the bleaching of flour was not within the inhibition of the statute, the purpose of the bleaching being to make bread whiter in appearance and therefore more pleasing to the eye. In this case white poppy seeds are darkened in order to give a contrast to the whiteness of the bread to which they are applied, for the same reason, to make the product more pleasing to the eye. In this respect their use is like the coloring used in candy.

[*Interstate Shipment Not Unlawful Because of Potentiality of Deception*]

There was evidence in this case that some baker used colored poppy seeds not as a decoration but mixed with the dough and that the coloring faded and darkened the finished product. But that experience was the result of a sale subsequent to the interstate shipment. If the public is to be protected against the sale of colored poppy seeds unlabeled or improperly labeled it will require state law and state administration. Federal authorities cannot construe the Act of Congress as forbidding the shipment of goods properly labeled merely because they may be subsequently sold without proper label or designation. If the inter-



state shipment is not a "palming off" of something inferior it is not in violation of the statute merely because it has a potentiality of deception. In the *Orange Juice* case above the court said:

"It is true that the beverage which the retailer thus prepares and sells is inferior to pure orange juice in its vitamin content, and the added color tends to conceal the weakness of the orange juice content, but this beverage is not shipped in interstate commerce, and its preparation and sale is not within the Food & Drugs Act." (96 F. (2d) 972, 3.)

In this case the same seeds may be sold by the retailer as were shipped in interstate commerce, but this court should not anticipate or presume that they will be sold fraudulently. This court having found that the seeds in this case were labeled and billed for what they actually were, should not determine that they are contraband merely because of the possibility that they might be used subsequently to deceive. The complaint is therefore dismissed and the seized goods are ordered returned to the defendant: owner.

### UNITED STATES v. WILLARD TABLET CO.

United States Circuit Court of Appeals for the Seventh Circuit. No. 8398,  
October Term, 1943, January Session, 1944. March 7, 1944.  
141 F. 2d 141.

There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the Government.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Even a court before which a Federal Trade Commission order is brought for review is bound by the findings of the Commission. To allow their finality to be attacked in a collateral proceeding would seem to run counter to the provisions and purposes of the Federal Trade Commission Act. Consequently, issues of fact tried by the Commission have a finality upon which *res judicata* may be predicated in a seizure action instituted under the Federal Food, Drug, and Cosmetic Act.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The doctrine of *res judicata* is not dependent upon mutuality of estoppel by judgment.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Holding that decisions of the Federal Trade Commission are *res judicata* in seizure proceedings, where the statements involved in both proceedings are the same, does not act as an impairment of the enforcement of the Federal Food, Drug, and Cosmetic Act.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

A contention of the Government that a plea of *res judicata* was directed to but one count of the libel and that it was entitled to a trial on the other count was not tenable, since the case was submitted by both parties on a stipulation of "all the facts." Inasmuch as suit had been tried upon the issue of *res judicata* as to the whole libel, the Government's contention to the contrary came too late.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

B. Howard Caughran, Indianapolis, Ind., for libellant-appellant.

John A. Nash, Arthur H. Schwab, Albert I. Kegan, all of Chicago, Ill., for claimant-appellee.

Before SPARKS and MAJOR, Circuit Judges, and LINDLEY, District Judge.



[Facts of Case]

MAJOR, Circuit Judge: The United States (libelant) instituted this proceeding for condemnation of a quantity of Willard's Tablets shipped in interstate commerce on the ground that the labeling thereof was false, in violation of the Food, Drug, and Cosmetic Act, 21 U. S. C. A. 352 (a), 352 (f), and the articles were therefore subject to seizure and confiscation (21 U. S. C. A. 334). The claimant filed an answer to the government's amended libel, setting up three affirmative defenses. The lower court sustained the claimant's defense of *res judicata*, based upon a prior proceeding before the Federal Trade Commission, and dismissed the action. From the order of dismissal, the government has appealed.

[Question for Decision]

The only question for decision is whether the proceedings before the Federal Trade Commission are *res judicata*, and, therefore, binding upon the District Court and determinative of the issues involved herein.

[Government's Contentions]

The government urges as a basis for overruling the lower court's holding that: (1) the issues herein involved were not determined by the Federal Trade Commission; (2) unaffirmed decisions of the Federal Trade Commission do not have the finality necessary to constitute *res judicata*; (3) there is no mutuality of estoppel; (4) the lower court's holding would impair the enforcement of the Food, Drug, and Cosmetic Act; and (5) the District Court improperly dismissed the amended libel as to that part alleging that the directions for use on the labeling were inadequate.

[Stipulated Facts Disclose Identity of Issues]

The facts as stipulated and adopted by the lower court effectively dispose of the government's first contention. The stipulation discloses: (1) that the statements relied upon by the government to uphold the charge of misbranding are identical with those approved by the Federal Trade Commission; (2) that the fundamental issue of fact as to whether the Willard Tablets would give the relief claimed was considered by the Federal Trade Commission. We, therefore, have the incongruous situation of one branch of the government approving the method now pursued by the claimant and another branch seeking to condemn. This is, to say the least, placing claimant in an embarrassing situation and should be avoided if possible.

[George H. Lee Co. Case]

In *George H. Lee Co. v. Federal Trade Commission*, 113 Fed. (2d) 583, the Circuit Court of Appeals for the Eighth Circuit upheld, and we think properly so, the defense of *res judicata*. Therein, the condemnation proceedings were instituted prior to the action before the Federal Trade Commission. The court on page 585 said:

"Although the remedies sought by the government in the two proceedings were different—condemnation in the first, and a cease and desist order in the second,—it is obvious that the alleged falsity of the representations of the petitioner with respect to the therapeutic value and effectiveness of its product constituted the main basis for each of the proceedings \* \* \*."

And further, on page 586:

"If the question of the falsity of the representations of the petitioner contained on its labels and circulars had been determined adversely to the petitioner in the libel proceeding, it could not have been heard to say in the proceedings instituted by the Commission that such representations were true. By the same token the United States and its instrumentality, the Commission, were not, after the decree in the libel proceeding, entitled to say that the representations made by the petitioner which had been finally adjudged not to be false, were in fact false. The government had had its full day in court on that issue, had lost its case, and could not collaterally attack, either directly or indirectly, the decree entered against it."

And on page 585, the court stated:

"Where the underlying issue in two suits is the same, the adjudication of the issue in the first suit is determinative of the same issue in the second suit."

[Sunshine Coal Co. Case]

As was stated by the Supreme Court in *Sunshine Coal Co. v. Adkins*, 310 U. S. 381, 402:

"A judgment is *res judicata* in a second action upon the same claim between the same parties or those in privity with them. *Cromwell v. County of Sac*, 94 U. S. 351. There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the government. See *Tait v. Western Maryland Ry. Co.*, 289 U. S. 620."



*[Findings of FTC Can Not Be Attacked in Collateral Proceeding]*

The government's second contention seems to rest solely upon the provisions of the Federal Trade Commission Act, as amended (15 U. S. C. A. 45 (b) (g)), that the Commission may, under certain conditions, modify its order after the expiration of time for appeal. Therefore, the contention is that such power of modification leaves an unappealed order without that finality essential to invoke the doctrine of *res judicata*. With this contention we do not agree.

The Act provides that an order of the Commission shall become *final* at the expiration of sixty days if no appeal is taken (45 (g)), and further provides for heavy penalties for violation of such order (45 (1)). It further provides that "the findings of the Commission as to the facts, if supported by evidence, shall be conclusive." Thus, even the reviewing court in the same proceeding is bound by the findings of the Commission. To allow their finality to be attacked in a collateral proceeding would seem to run counter to the provisions and purposes of the Act. As was said in the case of *United States v. Piuma*, 40 Fed. Supp. 119, 122:

"Is it the province of the court to try the truth or falsity of the defendant's advertisements already found to be false by the Commission? The answer to this question depends upon the meaning to be given the word 'final' as used in subsection (g). The purpose of the provision was to bring the doctrine of *res judicata* into the Federal Trade Commission's jurisprudence. \*\*\* This court will not now retry that issue."

With this construction of the Act we agree. We must, therefore, uphold the decision of the lower court that the issues of fact tried by the Commission have a finality upon which *res judicata* may be predicated.

*[Mutuality of Estoppel Not Involved]*

We agree with appellee's contention that mutuality of estoppel is not herein involved. We have held that the facts found by the Federal Trade Commission are conclusive and binding upon the District Court. The same result would obtain if the government were depending upon these findings to sustain its charge of misbranding. The doctrine of *res judicata* is not dependent upon mutuality of estoppel by judgment, as is contended by the government. The cases cited in support of this contention are not applicable to the instant situation.

*[FTC Decisions No Impairment of Food and Drug Act]*

What we have heretofore said sufficiently disposes of the argument that the decisions of the Federal Trade Commission should not be allowed to impair the enforcement of the Food, Drug and Cosmetic Act. Under the facts stipulated herein and to which this decision is limited, there can be no impairment of the enforcement of the aforementioned Act.

*[Plea of Res Judicata Directed to Whole Libel]*

The last contention of the government to be considered is that the plea of *res judicata* was directed to but one count of the libel and that it is entitled to a trial upon the other count, *i. e.*, upon the issue of whether the labels gave adequate direction for use. We are of the view that this contention is not tenable. As appears from the record, this case was submitted by both parties upon a stipulation of "all of the facts." The parties so understood it and so did the lower court. The suit was tried upon the issue of *res judicata* as to the whole libel, and the government's contention to the contrary comes too late.

*[Judgment Dismissing Libel Affirmed]*

The judgment of the District Court is affirmed.

## UNITED STATES v. 75 CASES, MORE OR LESS, EACH CONTAINING TWENTY-FOUR JARS OF PEANUT BUTTER, ETC.

United States District Court for the District of Maryland. Nos. 2084, 2092, 2101. February 2, 1944. Filed March 11, 1944. 54 F. Supp. 641.

Reversed, 146 F. 2d 124. See page 126.

Certiorari denied, 325 U. S. 856 (1945).

Section 704 of the Act provides for very broad inspection of a factory. Permission to inspect and to take photographs had been freely given by the claimant, and the inspector, consequently, did not go counter to the requirements of the law.

Section 704, Federal Food, Drug, and Cosmetic Act.



The provision in Section 703 for obtaining records of interstate shipment does not mean that records may never be obtained in some other manner, as from the shipper if he consents to disclose them. But it does mean that if the Government sees fit to bypass the prescribed method, then it must be careful to make full disclosure to the owner as to the purpose in asking for the records.

Sections 702 (b), 703, 704, Federal Food, Drug, and Cosmetic Act.

The use of the words "all pertinent equipment" in Section 704 was not intended to include a firm's books of accounts or financial statements or data of a firm's shipments.

Section 704, Federal Food, Drug, and Cosmetic Act.

In a seizure action against peanut butter alleged to be adulterated, the claimant-manufacturer moved to impound certain evidence and dismiss the libels on the ground that the Government inspector had not acted within his authority under the Act in copying data from interstate shipping records of the claimant. The motion should be granted since the court found, from the weight of the credible evidence, that there had not been such full and complete disclosure by the Government as to the use to which disclosure of the records would be put as it was required to make.

Section 704, Federal Food, Drug, and Cosmetic Act.

The Fourth Amendment is not a basis for relief in a civil suit such as a seizure action.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Carl Ross McKenrick, Assistant U. S. Attorney, Baltimore, Md., for plaintiff.

J. Charles Fagan, Baltimore, Md.; and Raymond M. Hudson, Washington, D. C., for defendants.

### Opinion (Oral)

#### [*Nature of Suit*]

COLEMAN, District Judge: This suit involves four consolidated libel proceedings under the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. Secs. 301-392), on the ground of alleged adulteration of certain shipments of peanut butter.

#### [*Motion To Dismiss Libels Granted*]

The motion of claimant to impound certain evidence and documents, to return the seized merchandise, and to quash and dismiss the libels, to which the Government has filed exceptions, must be granted for the following reasons.

#### [*Questions Presented*]

There are two questions in the case presented by the motion: first, whether the Government inspector acted within his authority and according to the requirements of the Act, as respects the inspection of claimant's plant on the dates in question; and, second, whether this same inspector likewise acted in accordance with the law in obtaining access to, and copying data from

interstate shipping records of the claimant which form the basis for these proceedings.

#### [*Inspection of Plant Proper*]

On the first question, I must rule in favor of the Government. Section 374 provides for very broad inspection of the factory itself, "and all pertinent equipment, finished and unfinished materials, containers and labeling therein," after first requesting and obtaining permission of the owner, operator or custodian of the factory to make such inspection. I find from the weight of the credible evidence that permission to do this was fully and freely given by claimant in the present case; that it is reasonable to assume that the results of such inspection might, without more, have led the Government to insist upon improvement within the plant, and that claimant might have inferred that such was a probable purpose implied in the inspection. Also, equally full permission was given to the inspector to take photographs in the plant, etc.; so, in doing so, the inspector did not go counter to the requirements of the law.



*[Manner of Inspecting Records Improper]*

On the second point, however, I feel that, while the case may be said to be a borderline one, the somewhat peculiar facts require the Court to rule in favor of the claimant.

Section 373 of the Act sets out, meticulously, the method by which records of interstate shipments shall be obtained for the purpose of enforcing the Act's provisions, which is that such records may be obtained *from the carrier* upon the request of an officer or employee duly designated by the Administrator under the Act. The provision does not mean that the records may never be obtained in some other manner, *i. e.*, direct from the shipper if he freely consents to disclose them, but I think it does mean that if the Government sees fit to bypass the specified method, then it must be very careful to make *full* disclosure to the factory owner as to the purpose for asking for the records. Clearly, the use of the words "all pertinent equipment" in Section 374 was not intended to include, for example, a firm's books of account or financial statements. *A fortiori*, it was not intended to include data of a firm's shipments, especially since the Section of the Act just preceding (Section 373) specifically provides how such data shall be obtained by the Government.

In the present case, I find from the weight of the credible evidence that there was no such full and complete disclosure as the Government was required to make. It is true the president of the company testified,—and I think his testimony is characterized by complete frankness, as also is that of the Government inspector,—that he gave permission to the inspector to look at the records, but there is no evidence of any conversation on any occasion, or any discussion between the inspector and the president of the company or any one else connected with the company, as to the precise use to which disclosure of the records would be put. Yet the information so obtained was made the basis of these proceedings, and is the *only* basis for them. That smacks of surprise, if not of actual misrepresentation, and I do not think that is a permissible way for the Government to proceed. It should follow the strict provisions of the law. It should not so combine a factory inspection with an examination of the records as might,—and as, I find in the present case, did, in fact—mislead the factory owner or operator as to just what use the Government might make

of the shipping data gleaned from these records. Possible damage to claimant's business reputation was likely to be involved in stoppage and seizure of its shipments in interstate movement,—far more damage than would normally be contemplated by imposing added sanitary requirements for manufacture of the product so shipped.

To summarize: I do not base the granting of the motion in this case upon a violation of the Fourth Amendment. The Government is correct in saying that the Amendment is not a basis for relief in a civil suit of this kind. See *U. S. v. 935 Cases more or less, etc.*, 136 Fed. (2d)\* 523, and cases therein cited. I rest my decision upon what I believe to be the proper interpretation of the Act as applied to the particular facts as I find them from the weight of the credible evidence.

For aught that appears, this proceeding might have been avoided, and the public interest equally and no doubt much more speedily served, if there had been a more complete, frank disclosure at the time to the president of the company as to just what would follow as a result of the examination of the records. It is true the inspector who examined the records was acting under direction of his superior, and it is not to be assumed that he had any ill-will or intention to misrepresent the situation. Yet, for aught that appears, there is reasonable ground to believe that the Government's position was misrepresented; and, in any event, where the Act says that investigators, before starting libel proceedings based upon interstate shipments shall obtain records in a certain way, they should either proceed accordingly, or should make complete disclosure to the factory owner or operator and be sure that his consent to examination of his records is not due in any respect to a failure to understand the full use to which the records might be put.

*[Motion Granted]*

For the reasons given, I will sign an order granting the motion to impound and to return the evidence taken from the records of the claims, which means a dismissal of the present proceedings, because it is based on information which I rule was improperly obtained. However, the shipments will be ordered to remain in the Marshal's custody for a period of fifteen days, pursuant to the Government's request, pending a determination by it as to whether or not to take an appeal.



*U. S. v. 7 Barrels "Spray Dried Whole Egg"**[Manner in Which Government May Proceed]*

I should add that my conclusion should not in any way hamper the Government or give any solace to the claimant if it be a fact that claimant has violated the law, because the Government still has a right to obtain from the carriers the records of in-

terstate shipments; to bring new libel proceedings, or, in lieu of that, on the basis of what evidence they may already have from *other* sources, to bring, if they see fit to do so, an equity proceeding for the purpose of having further shipment in interstate commerce by the claimant restrained.

**UNITED STATES v. 7 BARRELS, MORE OR LESS, EACH BARREL  
CONTAINING 190 POUNDS OF AN ARTICLE LABELED  
IN PART "SPRAY DRIED WHOLE EGG"  
UNITED STATES v. MARSHALL KIRBY & CO., INC.**

United States Circuit Court of Appeals for the Seventh Circuit. No. 8381.  
March 15, 1944. 141 F. 2d 767.

A contract for the sale of dried eggs provided that the product should be considered ready for inspection when an inspection certificate was issued. The buyer was entitled to receive that for which it had bargained, and the court must assume, in the absence of evidence to the contrary, that the seller, the claimant, did not intend that it should lose dominion of, or title to, its property before the required chemical analysis was reported.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

The object of the statute is to prevent adulterated articles of food from entering interstate commerce.

Section 201 (b), Federal Food, Drug, and Cosmetic Act.

After an inspection certificate for the seven barrels proceeded against had been issued, neither party insisted on a delivery, and seven other barrels were substituted and an embargo placed by the state on the rejected barrels. The rejected barrels hence could never become a part of interstate commerce.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

Goods may become a part of interstate commerce before transportation begins, and may remain such after transportation ends.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

In the instant case, however, the contract did not provide that the eggs segregated and marked prior to their test would then and there become a part of interstate commerce or that such acts would amount to a sale or delivery. The contract provided that the product should not be considered ready for delivery until the inspection certificate had been issued. Since the seven barrels of dried eggs proceeded against had not passed inspection, they never became a part of the product which the claimant had agreed to sell and were never introduced into interstate commerce.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

If the claimant had sold and shipped, or contracted to ship, the seven barrels of eggs to customers in another state, it would be held to have engaged in interstate commerce. However, under the facts of the case the claimant never sold or shipped, or contracted to sell or ship, the seven barrels of eggs to customers in another state.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

B. Howard Caughran and Paul A. Pfister, for libellant-appellee.

Arthur L. Israel, for claimant-appellee.

Before SPARKS, MAJOR and KERNER, Circuit Judges.



*[Nature of Action]*

SPARKS, Circuit Judge: The Government appeals from a judgment dismissing its libel for want of jurisdiction. The libel, alleging adulteration, had been filed against one lot of seven barrels of dried eggs which it sought to condemn under the provisions of § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a). The claimant by answer asserted ownership of the property and interposed two defenses, first, that the libel failed to state facts indicating that the article seized was introduced into or was in interstate commerce, at the time of the seizure, and second, that the article was not adulterated. The prayer asked for a dismissal of the libel and a return of the libeled goods to the claimant. The issue as to the second count is not before us, and, so far as this record discloses, it was not submitted at the hearing.

*[Question of Jurisdiction]*

It will be observed that the first count of the answer amounts to nothing more than a demurrer to the complaint, or a motion to dismiss it for lack of sufficient facts. However, neither the court nor the parties so considered it. The parties stipulated that the cause be transferred to the Indianapolis Division of the same District for trial and disposition, which was done. Without objection it was assigned for a day certain for hearing oral testimony, if desired by either party, and oral argument upon the first count of the answer, and a jury trial was waived. A stipulation of facts was filed, and both parties introduced other testimony at the trial. The District Court found the facts specially, rendered its conclusions of law thereon, and entered judgment for claimant dismissing the complaint for lack of jurisdiction. From that ruling this appeal is prosecuted. Under these circumstances we shall treat the question of jurisdiction upon the basis of facts found rather than those pleaded.

The statute relied upon to confer jurisdiction provides:

"Any article of food \* \* \* that is adulterated or misbranded when introduced into or while in interstate commerce \* \* \* shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found \* \* \*."

*[Contract Requirements]*

The subject of the libel was part of 150 barrels of spray-dried whole eggs tendered by appellee to the Federal Surplus Commodities Corporation in part performance of a contract between the parties. The contract here involved was in writing, consisting of four documents executed in the order named: (1) a printed announcement by FSCC that under certain named conditions it would receive and consider offers for the sale of spray-dried whole eggs intended for delivery at any stipulated time until December 31, 1942; (2) an offer by appellee to sell and deliver to the FSCC, at appellee's plant in Terre Haute, Indiana, all or any part of 66,690 pounds of spray-dried whole eggs, on the basis of the terms and conditions of the announcement; (3) acceptance by the FSCC of appellee's offer, and (4) appellee's confirmation of the acceptance.

The FSCC announcement consists of more than 21 pages of this printed record. It describes in minute detail the required content, character, and process of production of the eggs and their shipping containers. It required each shipping container to be marked by appellee, before testing the product and its removal from appellee's plant, with the following items of information: Name and type of the product; net weight; FSCC contract number; manufacturer's lot and container numbers; vendor's name and delivery-point address; and the month and year of manufacture. After testing the product, presently referred to, appellee was required to mark each container with the shipping instructions when and as furnished by the FSCC.

*[Rejected Barrels Embargoed]*

Sampling and inspection of the product to be tendered for delivery was required to be performed by the Agricultural Marketing Administration. For these services appellee was required to arrange with the AMA. The inspection and weight certificates were to be issued at the expense of appellee and delivered by it to the FSCC. All requirements of the contract as to marking were complied with by appellee except marking upon the 7 libeled barrels the name and address of the consignee. This was not done because they were rejected by the FSCC and as to them it furnished no legend in that respect. However, other barrels were substituted by appellee for those rejected and they were accepted. Four weeks



*U. S. v. 7 Barrels "Spray Dried Whole Egg"*

before this suit was filed, the Public Health Department of Indiana placed an embargo against the movement and control of the seven barrels. That order was in effect when this action was begun, and so far as this record discloses it is still in effect. The libeled product has never been removed from appellee's plant.

*[Government's Contentions]*

Appellant contends that the contract was a transaction in interstate commerce; that the barrels were marked and set aside as the property to be used in fulfillment of the contract, thus being brought within the exclusive dominion of the out-of-state purchaser, and thereby introduced into commerce within the meaning of the statute. It further contends that the subsequent rejection of the eggs did not remove them from the jurisdiction of the Act or divest them of their interstate character.

*[No Dominion of FSCC Over Eggs Before Acceptance]*

We are not in accord with these contentions. It is clear that the contract is quite conditional in its character. It consists of an accepted offer to deliver at appellee's plant, on or before a certain date, a prescribed amount of eggs of a described character. The eggs here libeled were part of a lot intended for delivery, if accepted, within the time, and at the place named in the contract, in part performance thereof. True, they were marked and set aside in seller's plant. However, they were not thus segregated as the property to be used in fulfillment of the contract, but for inspection and testing to determine whether they complied with the required specifications. This was necessary before there could be an acceptance of the delivery, and before acceptance there could be no dominion of the FSCC over the property.

*[Reasons for Preliminary Marking and Segregation]*

The contract provided that the product should be considered ready for delivery on the date the inspection certificate was issued, and not sooner. That provision definitely was of great interest to both parties, and each is entitled to rely upon it. The buyer was entitled to receive that for which it bargained, and we must assume, in the absence of evidence to the contrary, that appellee did not intend that it should lose dominion of or the title to its property,

or that the buyer should acquire either, before the required chemical analysis was reported. Certainly we can not assume that appellee, before such report, would intentionally cast its property into the channel of interstate commerce, thereby assuming the unnecessary risk of a lawsuit of this character. The plain and unambiguous language of the contract forbids such an assumption. It seems to us that the only reasons for the required preliminary marking and segregation of the barrels before the inspection and test was that actual delivery might be expedited after the acceptance, and the probability of substitution for any part of the tendered produce, without the knowledge of the FSCC, would be greatly minimized.

*[Rejected Barrels Could Not Enter Interstate Commerce Because of Embargo]*

It is quite apparent that the object of the statute is to prevent adulterated articles of food from entering interstate commerce. That object seems to have been fully accomplished long before this libel suit was filed. After the inspection certificate was issued neither party insisted upon a delivery of the seven barrels, and that was as early as a delivery could be made under Article 7 of the contract. Appellee thereupon substituted seven other barrels in their stead and the FSCC accepted them, whereupon the State of Indiana placed an embargo upon the rejected barrels, the effect of which was to prevent their removal from the plant. Hence they could never become a part of interstate commerce.

*[Cited Cases Distinguished]*

We recognize the legal principle that goods may become a part of interstate commerce before transportation begins, and may remain such after transportation ends. The cases bearing on the former enunciate the rule that where goods are purchased in one state for transportation to another, the commerce includes the purchase quite as much as it does the transportation. *Dahnke-Walker Co. v. Bondurant*, 257 U. S. 282. There defendant, a resident of Kentucky, contracted to sell and deliver his crop of wheat, F. O. B. cars in Kentucky, to plaintiff, a resident of Tennessee. Part of it was thus delivered, and payment was advanced for more than was delivered. The market price of wheat advanced, and defendant failed to deliver more. The action was for breach of contract and damages. The



selier defended on the ground that plaintiff, a foreign corporation, had not complied with the Kentucky statute with respect to doing business in that State, which was true. The buyer replied that the purchase and sale was a transaction in interstate commerce. The Court so found and held that the Kentucky statute was invalid as to that transaction because repugnant to the commerce clause, and damages for breach of the contract were awarded. There the specific wheat crop was unconditionally purchased, to be paid for upon delivery; the wheat was subject to no subsequent test; the terms of the sale and purchase constituted a completed transaction, subject to no variation, and at that moment it became a part of interstate commerce in strict compliance with the rule above referred to.

In the instant case, however, the contract did not provide, nor did the parties intend that the eggs segregated and marked prior to the test would then and there become a part of interstate commerce, or that such acts would amount to a sale or delivery of them. On the contrary, the contract provided that the product should not be considered ready for delivery until the inspection certificate was issued, and that eggs tendered for delivery must be accompanied by that certificate. Neither party knew whether they would pass inspection, and neither was permitted legally to sell or purchase eggs for interstate commerce which failed to pass inspection. Hence we conclude that neither title to nor dominion over any part of the eggs tendered for inspection passed to the FSCC until they were accepted, and since the seven barrels did not successfully pass inspection and were not qualified for transportation, and were never accepted, they never became a part of the product which appellee agreed to sell and which the FSCC agreed to purchase, and they were never introduced into interstate commerce. True, the FSCC accepted appellee's written offer to sell and deliver a specified amount of a certain kind

of eggs, but it never accepted any part of the eggs submitted for inspection until after they had successfully passed the test.

In support of its contention, appellant relies on *Hipolite Egg Co. v. United States*, 220 U. S. 45, and *United States v. 25 Packages of Hats*, 231 U. S. 358. In both cases the question at issue arose at the destination after transportation. We have no quarrel with the principles therein enunciated. However, they do not seem helpful in determining the question here where the sole issue involved relates to the events before transportation. Appellant also relies on *Carter v. Carter Coal Co.*, 298 U. S. 238, where the distinction was drawn in regard to federal jurisdiction between goods which were part of a contract of sale in interstate commerce and goods merely intended to be sold in another state. There the Court said: "One who produces or manufactures a commodity, subsequently sold and shipped by him in interstate commerce, whether such sale and shipment were originally intended or not, has engaged in two distinct and separate activities. So far as he produces or manufactures a commodity, his business is purely local. So far as he sells and ships, or contracts to sell and ship, the commodity to customers in another state, he engages in interstate commerce. In respect to the former, he is subject only to regulation by the state; in respect to the latter, to regulation only by the federal government."

[*Dismissal of Libel Affirmed*]

We have never questioned the soundness of that principle. It constitutes the basis of our conclusion. We are convinced that if appellee had sold and shipped, or contracted to ship, the seven barrels of eggs to customers in another state it would be held to have engaged in interstate commerce. However, our conclusion is that appellee never sold nor shipped, nor did it contract to sell or ship, to customers in another state the seven barrels of eggs in question.

AFFIRMED.



## UNITED STATES v. 70½ DOZEN BOTTLES, AND 76½ DOZEN BOTTLES OF "666"

United States District Court for the Middle District of Georgia, Valdosta  
Division. Civil Actions Nos. 112, 114. March 29, 1944. Notices of  
Judgment Under the Federal Food, Drug, and Cosmetic Act,  
Drugs and Devices (No. 1231) Issued June 1945.

An article was proceeded against on the ground that it was misbranded in that its name, appearance, cartons, etc., created in the minds of purchasers the impression that the article was the product which had been formerly sold as a treatment for malaria and had contained quinine, whereas the article no longer contained quinine. In instructing the jury, the district judge charged that the question was not whether wholesale or retail druggists were misled, but whether an average member of the buying public would be misled by the way the product was gotten up and handled.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The district judge further instructed the jury that if the jury believed that the container of the product was so made in size, coloring, etc., that the product would be misleading, in view of the impression which the public had theretofore had of the original product, then the jury should find in favor of the Government.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

### **Court's Charge to the Jury**

#### *[Misbranding Prohibited by Statute]*

DEAVER, District Judge: Gentlemen of the jury, an act of Congress known to some of us as the Pure Food and Drug Act, prohibits the shipment in interstate commerce of any drug—of course, there are a great many other things in the Act but I am confining it here to drugs because that is all we are interested in here—which is misbranded; and then the Act goes on to define the meaning of misbranded and it says that a drug is misbranded if the label is misleading. That is one instance in which it is misbranded. Then, it is misbranded if the container of the drug is so made or filled as to be misleading. Then another instance of misbranding is if a drug is an imitation of another drug. And another is, that if a drug is offered for sale under the name of another drug. The whole act is designed to protect the public, so that the public will not be buying one thing, thinking that they are buying another thing.

#### *[Charges of Libel]*

Now here the libel, as it is called—the paper filed by the government as a suit—alleges that this product which you have heard about here, the new product, is a misbranded drug; that there is and has been, the Government contends through a long number of years a product known and advertised to the public and well known to the public as three sixes or six hundred and sixty six or 666, and that the gen-

eral buying public have become acquainted with that product, whatever it is. They contend, as a matter of fact, that it contained quinine and iron and that the new product does not contain either; but the government contends that inasmuch as the old product of 666 containing iron and quinine was well known to the public and had been for years and years, that this product, this new product which does not contain iron or quinine, would under the circumstances which you have heard outlined in the evidence, the government contends, cause the general public to buy this new product, thinking they were obtaining the old product. In general, that is the contention.

#### *[Issue Between Claimant and Government]*

The Monticello Drug Company comes into the case—of course, this case originated by the seizure of certain bottles of this product by the government and then this paper that I referred to, called a libel, which is a paper asking the court to condemn the seized product, it is really a proceeding against the product itself, but under the law the interested party, that is the Monticello Drug Company, has a right to come into the case and defend. The papers, if you want to look at them, denominate the Monticello Drug Company as the intervenor and in some cases as the claimant, that is the claimant of the product seized—But in any event, the Monticello



Drug Company came into the case, as it had a right to do, and defends against the condemnation of this seized product, and that is the issue. The issue is between the government and the Monticello Drug Company as to whether this product is under the circumstances misbranded or not in any of the respects which I mentioned.

*[Preponderance of Evidence; Burden of Proof]*

Now, the question is to be decided by this jury and you are to decide the case from a preponderance of the evidence in the case. A preponderance of the evidence is just that greater weight of the evidence which inclines the mind of a reasonable man to one side of an issue rather than to the other side. The burden is on the government to show that this new product, which has been seized, is misbranded in at least some one of these respects which I have mentioned. You will apply the evidence to the law, as I have stated it in these various respects, and say whether, in your opinion, the evidence does show that the product was misbranded in any one of these different ways.

*[Similarity of Color and Design of Container Charged as Misleading]*

Now, the first way I mentioned to you is that it is misbranded if the label is misleading. Well, I want to make that division of the suit clear to you. I may state to you, I think, that if a purchaser or anybody else of average intelligence should actually take the label on the new product and read it, that the label in and of itself and without more would not be misleading because the label itself does state what the drug contains. But the government goes further on other grounds and says that the drug is misbranded in that the method in which it is dressed up, the container, the box or paper carton, whatever you want to call it, is so colored and so designed with the figures 666, and the color of the product and the well known former product of 666, that all of those things taken together would mislead the average member of the public who calls for 666 in any store where it is available.

*[What Jury Is To Pass On]*

Now, before I elaborate at all on these, I think that inasmuch as the evidence has taken a very wide latitude and certainly the arguments of counsel on both sides have

taken a very wide latitude, I conceive it to be my duty under those circumstances to try to put before this jury exactly what it is you are to pass on.

*[Question Is Whether Public Is Misled]*

A great many things have been argued here in this case on both sides that haven't really got anything to do with the question that you are to decide. Of course, it is properly a matter of the history of the case here to show that when the war came along and quinine had to be restricted for military use, except in malaria, and that a certificate had to be had before it could be sold for malaria, that is all properly before you, but that is not the question that you are to decide: and the question moreover is not whether the wholesale druggist and retail druggist were advised that a change had been made. That is not the point in the case either. There is evidence here that the Monticello Drug Company did inform certainly a large part, if not all, of the wholesale druggists and the retail druggists that a change had been made in this product and specifically called their attention to it. But that is not the question that you are to decide, whether a wholesale druggist or the retail druggist knew about it. If they didn't, they might be innocent of selling something that was not what they thought it was, or if they did know the difference and sold it nevertheless without complying with the law, why some of the druggists might be guilty, but that is not the question for you to decide here. We are dealing here with the question of, not whether the wholesale druggist was misled, not whether the retail druggist was misled, we are dealing here with whether under all the facts and circumstances an average member of the buying public who was not informed would be misled by the way this product is gotten up and handled.

*[Claimant Not Prevented from Using Trade Name 666]*

Something was said too here in argument—and that is the only reason that I mention it—that if you were to find in favor of the government and against the Monticello Drug Company, that would prevent the Monticello Drug Company from using their trade name, 666. Well, I didn't stop counsel in the argument because I intended at least to try to make it clear to the jury. Your finding, no matter which way it is, will not prevent the Monticello Drug Com-



pany from using its trade name 666. No attack is made in this case on that trademark and certainly the old product of 666, when the war is over and the ingredients can be obtained for that product, can be manufactured and again put on the market for people with malaria or anything else as for that matter they want to buy it for. There is no reason, so far as your verdict is concerned, why they can't continue to do that right on. The effect of an adverse verdict against the Monticello Drug Company, so far as this suit is concerned would be that it would prevent the Monticello Drug Company from putting out and selling to the public this new product under the name, if you find that is true, 666, which would mislead the buying public into thinking they were buying the old product. If you found a verdict against the Monticello Drug Company, then they could not keep on putting up this new product in the same form and with the same lettering and with the same figures and under the same circumstances that we have heard about in this case. They could not keep on doing that but the government contends that that is the very thing that they ought not to do, is to put this product on the public under circumstances which would lead the public to believe that it is the old 666.

*[Misbranded Drug Need Not Be Destroyed]*

And then too, if I am wrong the Food and Drug agents here can correct me, but if you find a verdict against this product or against the claimant to it, then, as has been done in numerous other cases where the product itself is not in and of itself objectionable, it would not necessarily have to be destroyed or withdrawn and not used or lost utterly. I know that in a great many food cases and drug cases this is the result, that if you have a food case and the food is rotten or poison or unfit for use for any purpose, then, of course, it is destroyed, where it is condemned. It is destroyed because it is not fit for use and can't be used for any purpose; but if some food product is shipped in violation of the Food and Drug Act, but nevertheless may be properly used for some purpose in some other way, then by an arrangement and under the supervision of the Food and Drug people, the owner or the claimant of such food as that would be permitted to rework it, so to speak, under the supervision of the Food and Drug Agency; and if it could be used for some proper purpose, than the Food

and Drug agent would cooperate in reworking or supervising the reworking just to see that it is properly used.

*[Misbranded Drug Could Be Sold in Another Form]*

So, in this case, so far as this suit is concerned, no attack has been made on this new product itself as a cold remedy or for any purpose as for that matter. No attack has been made on the drug itself. It may or may not have proper uses; we just don't know anything about that and are not particularly concerned with it. It may be a product that could be used and it might be a good product, but the question here is not whether it is a good product or not. That is not the question at all. But if it is a good product, then the effect of your verdict would be to prohibit the sale of it in this present form. If you think it would mislead the public, then your verdict against the Monticello Drug Company would prevent them from selling this package that you have seen here in its present form and with its present coloring just as it stands now, would prevent them from selling that under this name 666, because your verdict would mean that you think that the sale of it with its present get-up, dressing, boxing and present coloring in connection with the previous reputation of the old product and all the other facts and circumstances in this case, your verdict would mean that you think that to sell that product now under that name and style and get-up would mislead members of the buying public; and if you found such a verdict, it would prevent the Monticello Drug Company from continuing to sell it in that present form, and so far as I know, that is the only effect your verdict would have, except of course to destroy these bottles that have been seized, if the Monticello Drug Company did not ask to have them returned and reworked and sold in some way or other that would not be misleading. But I know of no reason why they could not take all of this product that is bottled at present in that form, why they couldn't take that back and put the same product out under some form or other that would not be misleading.

*[Jury Sole Judge of Evidence]*

Now, gentlemen, the question is for you to decide and you are to decide it from what you have heard in the evidence itself. You are the sole judges of what the evidence shows. I could review the testimony on



both sides and I could even tell you what I think about it; I could express an opinion about what I think about it under the practice in this court but I doubt if that would be helpful because, after all, even if I did, you would not be bound by any opinion that I might have about the evidence. The law provides that you should accept without question the law that I give you, that whatever I tell you is the law, you are supposed to take that; but so far as the facts are concerned, you are not bound by anybody's opinion, including my own. If I should express one—as a matter of fact, I am not going to express one, I don't think it would be helpful at all—but you are to decide whether this product here, this new product is misbranded in any of the respects contended by the government.

*[Verdict for Government If Product Misleading]*

Now, if you think, under the second section that I stated to you in the beginning, if you think that the container of this new product is so made in size and color, lettering and figures, that it is so made and the container so filled and colored, in connection with whatever reputation you may think the old product previously had, if you think that because of the container fixed up as it is and the product colored as it is, in view of the impression which the public has heretofore had of the original 666, if you think under all the circumstances that this product, if put out to the public, would be misleading, then you would find in favor of the government, because that would mean that this product here, under the definition which I have given you and which is in the statute itself, would be misleading.

*[Drug Misbranded If New Product in Imitation of Old 666]*

Or, if you think that this new product, because of the way it is handled and bottled and dressed up and colored, if you think that the new product is being offered for sale or sold to the public in imitation, as just a drug in imitation of the old original 666, but is not the old 666; in other words, if you think that the new drug is just an imitation of the old 666 and under all the facts and circumstances that it is not the old 666 but is an imitation of the old 666, then it would be misbranded under this act.

*[Drug Misbranded If Offered for Sale under Name of Another Drug]*

Or, somewhat similarly, that if it is offered for sale under the name of another drug. You see the second thing that I mentioned to you there was if it is an imitation of another drug. Now, this one is slightly different. It says that if it is offered for sale in the name or under the name of another drug. Now, that would mean that if you think that this product, this new product, is not the same as the old original 666, but that it is being offered for sale to the public under the name of the old original 666, then it would be offered for sale, one drug would be offered for sale under the name of another drug, and if that is in your mind, under all the circumstances, likely to mislead the average member of the buying general public who buy this medicine, if you think from all the circumstances you have heard in this case, that the average member of the buying public who go to stores and call for this medicine 666 would likely be misled into accepting the new product under the impression that they were obtaining the old product, that would amount to misbranding and you would find then in favor of the government.

*[Financial Loss to Claimant Immaterial]*

Now, of course, the question here is not a question of whether it would be harmful financially to the Monticello Drug Company. Whether it would entail a loss, of course, I do not know about that and I do not suppose you do. What loss would be entailed if they had to take this product back and rework it or even if it was destroyed, I do not know. But that is not the question that you are to pass on. It might, even if it did entail a loss to the Monticello Drug Company, and regardless of what that loss might be, still if they are as a matter of fact putting out a misbranded product, why you would not be concerned with whether they lost or whether they didn't. Your only question, that is what I am trying to say, your only question is whether the Monticello Drug Company is putting out an article, this new 666, whether they are putting out an article that is misbranded, and by that I mean misbranded or handled in the ways that I have mentioned here that would mislead members, average members of the buying public. If they are doing that, then you ought to find that and if they are doing it, then you ought to find against them.



*[Verdict for Claimant If No Danger of  
Public's Being Misled]*

If, in your opinion, on the other hand, under all the evidence in this case the get-up, color, lettering, container and everything that you have heard about in this case would not be misleading to the average member of the public who buys 666, not misleading, why then, of course, there is no reason for stopping the Monticello Drug Company from putting it out in this form; and if you think that is true, you ought to find in favor of the Monticello Drug Company, which would mean that this product may be handled in the same way that it is being handled up to the time of filing this suit. That would mean that, in your opinion, under the evidence that there is no real danger or likelihood that members of the public would be misled by it, and that if they bought it, they would know what they were getting and would not be misled; and if that is what you think about it under this evidence you ought to find in favor of the Monticello Drug Company.

*[Question for Jury]*

So, that is your question. I state it finally that your only question is this: Is this new product under all the facts and circumstances that you have heard about in this case and under the definition which I have given you from the law, is this product a misbranded product? If it is, you ought to find in favor of the government. If it is not, you ought to find in favor of the Monticello Drug Company.

*[Form of Verdict]*

Now, if you find in favor of the government, just write somewhere on the papers which you will have out, "We the jury find—if you think it is a misbranded article—we the jury find in favor of the United States." I believe that is the way the plaintiff is designated. On the other hand, if you think that this article is not misbranded in any of the ways which I have discussed with you and not misleading then you ought to find in favor of the Monticello Drug Company, and the form of that verdict would be, "We the jury find in favor of the Monticello Drug Company," then date your verdict and let your foreman sign it.

*[Sales Under Name of Another Drug]*

Mr. Davis. "Your Honor please, in your recapitulation there, you probably inadvertently overlooked that if it was sold under the name of another drug, it was misbranded. It would not have to be misleading but if it is actually sold under the name of another drug, it would be misbranded."

The Court. "Very well. I will see counsel in the office before the jury retires."

*[Exceptions]*

(In the court's chambers)

The Court. "All right, any exceptions you want to get in the record?"

Mr. Ashby. "Doesn't the government proceed first?"

The Court. "Well, doesn't make any difference to me?"

Mr. Walker. "I think in the last two subdivisions, under sub-section 'i' that if it is offered for sale under the name of another drug, then it doesn't have to be misleading."

The Court. "It technically might not but the whole object of that part of the statute would be to keep from misleading anybody, I think."

Mr. Davis. "Well, you may be right about that."

Mr. Ashby. "Your Honor, the Intervenor takes exception to so much of the court's charge as submits to the jury any issue of whether the product here involved, the drug here involved, is in imitation of another drug; and likewise takes exception to such portion of the charge as submits to the jury the question of whether or not the drug here involved is offered for sale under the name of another drug. I have already argued that, Your Honor. I just make the point again."

The Court. "All right."

*[Verdict]*

(Returning to the Court-room)

Gentlemen of the jury, you may retire to the juryroom the Marshal will show you.

[The jury, after deliberation, returned a verdict for the Government. On April 1, 1944, judgment was entered condemning the product and ordering that it be destroyed.]



UNITED STATES v. 503 $\frac{3}{4}$  DOZEN BOTTLES, MORE OR LESS,  
 OF "SULFA-SEB", AND 173 $\frac{3}{4}$  DOZEN BOTTLES, MORE  
 OR LESS, OF "SULFA-PED"

United States District Court for the Western District of Missouri, Western  
 Division. No. 1648. Filed April 3, 1944. 54 F. Supp. 759.

If the labeling of a drug product proceeded against is false and misleading in any particular, the preparation has been misbranded.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

In determining whether the representation on a label is false and misleading in any particular, all the language of the label must be considered.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

The words "For Hair and Scalp" on a label represented that the preparation, when used as directed, was beneficial to the hair and scalp, but not that it was a panacea for every possible disease that might attack the hair or scalp.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

In a suit brought against a drug based on alleged misbranding, scientific testimony, not the testimony of laymen, is the testimony that counts.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

In a suit against a hair and scalp remedy, "Sulfa-Seb," and a foot remedy, "Sulfa-Ped," based on alleged false and misleading therapeutic claims, the effect of the scientific testimony offered by the Government was overwhelming, and the articles should be condemned.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Letters received from purportedly satisfied customers to questionnaires mailed out by claimants were hearsay and not admissible.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Scientific treatises were not competent evidence.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Evidence did not warrant condemnation of "Sulfa-Seb" and "Sulfa-Ped," products containing sulfanilamide, on account of failure to include warnings of dangers incident to the use of the preparations.

Sections 304 (a), 502 (f), Federal Food, Drug, and Cosmetic Act.

**Memorandum Opinion, Findings of Fact,  
 Conclusion of Law, Judgment and  
 Decree**

*[Charges of Information]*

MERRILL E. OTIS, District Judge: The amended information in libel in this proceeding was filed February 14, 1944. It makes reference to two preparations, one known as "Sulfa-Seb", the other as "Sulfa-Ped". The charge is that these preparations are misbranded within the meaning of Title 21, U. S. C., Section 352. That section provides *inter alia* that a drug "shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular" and that it "shall be deemed to be misbranded (f)

unless its labeling bears . . . such adequate warnings . . . against unsafe dosage or methods . . . of administration or application, in such manner and form, as are necessary for the protection of users; . . ."

The information charges that the labeling of the preparation known as "Sulfa-Seb," which reads, in part, "For hair and scalp . . . Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair," is false and misleading in the following respects: that the article (1) is not an adequate treatment for disease conditions of the hair and scalp; (2) that it is



not fungicidal; and (3) that it will not control conditions resulting from infection around the follicles of the hair.

The information charges that the labeling of the preparation known as "Sulfa-Ped," which reads, in part, "A new treatment for Athletes Foot . . . Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet . . .," is false and misleading in that the preparation is (1) not a treatment for athlete's foot; (2) is not a fungicide; and (3) will not relieve discomfort and treat and control conditions identified with fungus and bacterial conditions of the feet.

The information alleges that both preparations are misbranded for that the labels contain no such adequate warnings "as are necessary for the protection of users since the articles contain sulfanilimide" and no warnings that "their use [*i. e.* of the preparations] should be discontinued if a new skin rash appears or if the skin condition under treatment becomes worse."

[*Sulfa-Seb Label Considered as a Whole*]

We begin this memorandum by first discussing the first charge in the information, that the preparation known as "Sulfa-Seb"

is false and misleading in the respects indicated in the information.

1. There has been no real controversy in the case between counsel for plaintiff and counsel for claimant touching the applicable law. The language of the statute is clear enough. If the labeling "is false and misleading in any particular" the preparation bearing the label has been misbranded. Obviously it is necessary first of all to determine *what* representation is made by the label and to determine whether *that* representation is false and misleading in any particular. It would seem to be obvious, moreover, that in determining whether the representation on a label is false and misleading in any particular *all* the language of the label must be considered. None would contend that single words or phrases should be lifted out and that if those words or phrases separately considered can be found to be untrue, then the preparation should be condemned as misbranded. Single words or phrases might be so explained by other language as that there is no misrepresentation whatever. Fairness requires that the whole legend upon the label of "Sulfa-Seb" should be set out so that the label may be considered as a whole. Accordingly, we do set out the label by inserting at this point one of the labels:

<b>A SULFA-DRUG COMPOUND</b>		
<p><b>SHAKE WELL BEFORE APPLYING</b></p> <p><b>ALSO CONTAINS</b> Pheno] (less than 1% by volume) and other inert ingredients in varying amounts.</p> <p><b>GUARANTEE</b> Return for refund must be made within 2 weeks of purchase.</p> <p><b>EXTERNAL USE ONLY</b></p>	<p><b>FOR HAIR AND SCALP</b></p> <p>A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair.</p> <p><b>ACTIVE { Sulfanilamide</b> <b>MEDICANT { ¼ GRAM TO EA FL. OZ.</b></p> <p>Distributed by <b>SULFA PRODUCTS CO.</b> 1125 Grand Ave. Kansas City, Mo.</p>	<p><b>SHAKE WELL BEFORE APPLYING</b></p> <p><b>DIRECTIONS FOR USE</b> Massage thoroughly into scalp. Comb out loosened scale using fine tooth comb. Use often as necessary to keep scalp moist with preparation. If hair is left too oily from treatment, remove excess oil by brushing. Set and groom with wetted comb. Wash hair no oftener than once a week.</p> <p>Content 4 Fluid Ounces \$2.50</p> <p><b>EXTERNAL USE ONLY</b></p>
MFG. BY — SULFA PRODUCTS COMPANY OF AMERICA — DIV. NU BASIC PROD. CO., ROYAL OAK, MICH.		

Any one who inspects this label will at once discern that it contains much language which is not charged as being false or misleading and which obviously is not false or misleading. Some of the language is devoted to precise directions as to how the

preparation is to be used. Some of it is a guarantee of return of money. A part of it is a warning that the preparation is "for external use only". Some of it describes accurately all of the ingredients in the preparation. Much of that part of the



legend which is the object of the government's complaint is in type so small that it would almost certainly escape being read by any ordinary purchaser. The most prominent part of the label is *the name* of the preparation, "*Sulfa-Seb*," a name which certainly means nothing and conveys no significance. In somewhat smaller type, and yet in legible type as distinguished from the minute wording of the rest of the label, are the words "FOR HAIR AND SCALP." Here is the real representation which is made to the purchasing public. Nine out of ten of the purchasers of this preparation in all probability would read no other part of the label than the words in conspicuous letters "FOR HAIR AND SCALP." (What advertising, what circular, what verbal recommendations may have influenced purchasers we do not know but very reasonably we may conclude that an intention to purchase was formed *before* the label was read.) Let us then first consider whether the FOR HAIR AND SCALP is false and misleading.

[*Implication in Words "For Hair and Scalp"*]

We agree at once with the contention of the Government in this case that there is an implication in the words "FOR HAIR AND SCALP" which constitutes a part of the meaning to the ordinary observer and purchaser. By the use of these words it is represented that the preparation, when applied externally and in the manner prescribed by the directions on the label, is *beneficial* to the hair and scalp, that the use of the preparation will promote the health of the hair and scalp. To say, however, that the words "FOR HAIR AND SCALP" alone (as was said in the argument by learned counsel for the Government) would mean to an ordinary observer that the preparation was a *panacea* for every possible disease that might attack the hair or scalp seems to us grossly to distort the meaning which the reader would derive from the language employed. The reasonable interpretation of the words, considered alone, is that the use of the preparation in the manner directed will benefit the hair and scalp when affected by such commonly known maladies as those causing, for example, dandruff, falling hair, threatening baldness.

When we descend from the words in large type, "FOR HAIR AND SCALP," into the legend minutely printed beneath them, we are given the more specific information that

the preparation is "Designed as a fungicide to relieve itching" and that it is "Designed as a fungicide to treat and control the condition resulting from infection round the follicles of the hair." Here the words that would mean anything to the ordinary reader and observer (the word "fungicide" would mean nothing except to the rare individual) are the words to "relieve itching" and the words "to treat and control the condition resulting from infection around the follicles of the hair."

The impression then created by this label on the ordinary purchaser and observer, if he reads only the conspicuous words, is that here is a preparation that will be helpful in dealing with such common maladies as dandruff, falling hair, etc., and, if he descends into the minute type, that here is a preparation that will relieve itching in the scalp and that will beneficially affect a condition resulting from infection in the scalp.

With such an interpretation placed upon the label, and we believe it is a fair interpretation, not a far fetched and distorted one, the question is, is this preparation one which will benefit the hair and the scalp with respect to the common maladies referred to and is it a preparation which will relieve itching in the scalp and will benefit conditions resulting from infection in the hair? If the preparation will do these things it certainly cannot justly be condemned as falsely labeled.

[*Testimony of Laymen of Slight Value*]

2. The evidence in the case was of two general classes, the testimony of experts and the testimony of laymen. The testimony of the laymen called by the Government (there were only a half dozen of these) chiefly related to the charge of misbranding for failure to warn of dangers. It did not particularly bear upon the charge which we now are especially considering, namely, was the label of "Sulfa-Seb" false and misleading. The testimony of the laymen who testified for the claimants (there were fifteen of these) did directly bear upon this charge, either as against "Sulfa-Seb" or "Sulfa-Ped." But the testimony of a few laymen, however honest that testimony may be (and we regard the testimony of each of the laymen appearing in this case as entirely honest) is of slight value upon the issue under present discussion. There were many thousands of users of these preparations. The evidence indicated that there



were hundreds of users even in Kansas City. That a small number experienced unsatisfactory results, which they ascribed to some deficiency or injurious element in the preparation, and that a small number experienced satisfactory results which they ascribed to the preparation, is of small significance. The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little. We would not say, of course, that if we were dealing with and had the results of tens of thousands of cases, we would not have something significant. A few dozen instances are of such trifling value as that they can almost entirely be disregarded.

[*Scientific Testimony Counts*]

The scientific testimony in a case of this character is the testimony that counts. Scientific testimony is available to support any meritorious cause, even, as we know, when the leading physician in a community or the American Medical Association itself is under attack. Of course, scientific testimony is available to the Government in support of any meritorious cause presented by the Government. The Government has its official staff of scientists of outstanding ability and the government is able to obtain the services of other scientists of outstanding ability. But private individuals also are able to obtain the testimony of outstanding men of science *provided there is real merit in their cause*. Claimants in this case had the financial ability to obtain testimony. But they put only one so-called expert (we use the word "so-called" advisedly) on the stand. They brought him from San Antonio, Texas, to Kansas City and paid him, according to his testimony, at the rate of \$100 a day and, we suppose, his expenses also. (We judge that was the zenith of his professional earnings to the present date.)

[*Scientific Testimony of Government Overwhelming*]

The testimony of the young M. D. brought by claimants from Texas was pitifully weak. His qualifications were unsatisfactory, his experience in the practice of medicine was brief and limited, his knowl-

edge of the science of the subject under inquiry was obviously slight. He could say "Yes" to leading questions, but if he had been asked to discuss the sciences involved he would have floundered hopelessly. He was spared, if not by merciful counsel (who also were floundering) at least by a merciful court.

There was a reason for the complete failure of the claimants to support their contentions by outstanding expert testimony. That testimony just was not procurable. The failure of the claimants in this respect impressed us as almost the equivalent of a confession of the general accuracy of the testimony of the Government's experts. The general effect of that testimony was that while the preparation "Sulfa-Seb" might have some slight temporary value in some instances by way of relieving an itching scalp or by way of temporarily removing dandruff, it had no real value with respect to any malady of the scalp, whether generally and commonly known or obscure in character and difficult to diagnose. The general effect of the testimony of the experts for the Government, whose qualifications were outstanding, was certainly to the effect that the preparation known as "Sulfa-Seb" constituted no kind of a treatment or control for infection in the scalp and round the follicles of the hair. We are bound to say that the effect of the scientific testimony offered by the Government was overwhelming *as against the complete emptiness of the scientific testimony offered by the claimant*.

[*Benefits of Sulfa-Ped Exaggerated*]

3. Much of what we have said concerning the preparation known as "Sulfa-Seb" is equally applicable to the preparation known as "Sulfa-Ped." We set out here the exact label of "Sulfa-Ped" which the Government has attacked. There cannot be any objection to much of this label. Most of it is entirely true and accurate. But we have reached the conclusion that there is some exaggeration in the label in that part of the legend in which it is represented that the preparation is a beneficial treatment and a control for "the conditions identified with fungus and bacterial conditions of the feet."



<p><b>SHAKE WELL BEFORE APPLYING</b></p> <p><b>ALSO CONTAINS:</b> Phenol (less than 1% by volume) and other inert ingredients in varying amounts.</p> <p><b>GUARANTEE</b> Return for refund must be made within 2 weeks of purchase.</p> <p><b>EXTERNAL USE ONLY</b></p>	<p><b>A SULFA-DRUG COMPOUND</b></p> <h1 style="text-align: center;">SULFA-PEO</h1> <p style="text-align: center;"><b>A NEW TREATMENT  FOR ATHLETES FOOT</b></p> <p>A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet.</p> <p><b>ACTIVE 1 Sulfanilamide</b> <b>MEDICANT 1 1/2 GRAM TO EA. FL. OZ.</b></p> <p>Distributed by <b>SULFA PRODUCTS CO.</b> 1125 GRAND AVE. KANSAS CITY, MO.</p>	<p><b>SHAKE WELL BEFORE APPLYING</b></p> <p><b>DIRECTIONS FOR USE</b></p> <p><b>Chronic Cases</b> Massage well into affected parts, morning and night. Take daily foot bath in warm water before applying night application. Use only mild soap.</p> <p><b>Acute Cases</b> Puncture blisters and permit fluid to drain out. Soak in warm water using mild soap. Dry thoroughly. Apply and cover with white cotton band. Use new footwear.</p> <p><b>CONTENTS: 4 FL. OZS.</b> <b>\$2.50</b></p> <p><b>EXTERNAL USE ONLY</b></p>
--	--	--

**MFG. BY — SULFA PRODUCTS COMPANY OF AMERICA — DIV. NU-BASIC PROD. CO., ROYAL OAK, MICH.**

### Certain Matters of Evidence

4. During the trial of the case there was offered in evidence by claimants a large number of letters (responses received from purportedly satisfied customers to questionnaires mailed out by claimants). We refused to receive these letters in evidence for reasons which were stated at the time of the ruling. Such letters are so obviously hearsay that the matter of the propriety of the ruling does not seem to us to be at all debatable. No question of the good faith of the manufacturers or of the claimants is involved in this proceeding. The proceeding is not brought against individuals. The proceeding is against inanimate preparations. The preparations, not individuals, are attacked. There is no reason to question the good faith of any one in this proceeding. We believe the claimants did act in good faith. The only question in the case is, are the labels on the bottles false and misleading in the sense that the information conveyed by them to ordinary readers is erroneous.

Another matter of evidence, which was taken under submission, is made up of a number of exhibits, being claimants' Exhibits 14 to 21, inclusive. Objection was made by the Government to the reception of these exhibits. The exhibits were scientific treatises, each of which discusses the uses of sulfanilamide. None of them purport to discuss the particular preparation involved in this proceeding. It seems clear to us that these exhibits were not competent in evidence. The reasons for that conclu-

sion are elementary. Undoubtedly in the cross examination of an expert witness he may be asked whether he agrees or does not agree with certain statements contained in reputable treatises. There is no convincing authority, however, for the view advanced by learned counsel for the claimants in this case, to-wit, that *as affirmative proof* treatises may be offered in evidence. If the testimony of Dr. X, for example, is desired by a party, he can call him as a witness so that he can be cross-examined in court. If he is beyond the jurisdiction of the court, undoubtedly the party can take his deposition, when again he may be cross-examined. But it is unthinkable that a party may have some witness (in this instance it was a layman) say that Dr. X is an authority in a certain field and then to offer in evidence some book or treatise which may have been written by Dr. X.

Notwithstanding our views of the law in this regard are very clear, we have read all of the exhibits referred to which were offered in evidence by the claimants. *For the purposes of this case we overrule the objection to these exhibits.* Nothing contained in the exhibits affects the findings of fact which we shall hereafter make. Findings of fact are made as of the time when the information in libel was filed. What may have been the view of scientific men on dates earlier than that date, of course, is not controlling. The knowledge of scientists, especially in a field so new as that which deals with the sulfa drugs, is a growing knowledge. The science is in the process



of evolution. The best views of the ablest scientists two or three years ago may not be especially valuable now.

#### Matter of Warnings

The charge of inadequate warnings upon the labels was an after thought. The original information in libel did not contain that charge. We are satisfied that the evidence does not warrant condemnation of the preparations on account of failure to include warnings.

#### Findings of Fact

1. The label "Sulfa-Seb" is false and misleading in that it represents that the preparation labeled is a remedy effective as a treatment for the commonly known maladies affecting the scalp and hair, whereas its only value is in relieving an itching scalp and in temporarily, in some instances, removing dandruff, and it is false and misleading in that it represents that the preparation labeled is a treatment or control for infections in the scalp and round the follicles of the hair.

2. The label "Sulfa-Ped" is false and misleading in that it represents that the preparation labeled is a treatment of and will control the conditions identified with fungus and bacterial conditions of the feet.

3. Neither the labels of "Sulfa-Seb" or "Sulfa-Ped" is misbranded in that it does not contain an appropriate warning of dangers incident to the use of the preparations.

#### Conclusion of Law

The prayer of the amended information in libel should be granted. The labels on the preparations known as "Sulfa-Seb" and "Sulfa-Ped" seized by the marshal should be condemned. The false and misleading labels on such preparations should be destroyed.

#### Judgment and Decree

This cause coming on to be heard before the Court, trial by jury having been waived by the parties, and the Court having considered the pleadings, the evidence introduced, the argument and briefs of counsel, and being fully advised in the premises:

It is by the Court ordered, adjudged and decreed that the labels used on the bottles of "Sulfa-Seb" and the bottles of "Sulfa-Ped" seized by the marshal be condemned and destroyed.

It is further ordered, adjudged and decreed that when the labels have been destroyed, the bottles and the preparations therein be turned over to the claimants for such further use thereof as the claimants lawfully may make.

It is further ordered that the costs of this proceeding, together with the cost that may be incident to removing and destroying the condemned labels and returning the unlabeled bottles to claimants, shall be paid by claimants.

---

### ARNER CO., INC. ET AL. v. UNITED STATES

United States Circuit Court of Appeals for the First Circuit. No. 3928.

May 4, 1944. 142 F. 2d 730.

Certiorari denied, 323 U. S. 730 (1944).

There would be no need to provide for the promulgation, under Section 503 (a) of the Act, of regulations exempting bulk shipments of drugs from labeling requirements under designated conditions if the labeling requirements applied only to retail packages.

Section 503 (a), Federal Food, Drug, and Cosmetic Act.

The passing of title in the state of origin does not remove from the coverage of the Act a drug which is misbranded when shipped in interstate commerce.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

The arrangements that are made between seller and purchaser with respect to the place of taking title to a commodity, or as to the payment of freight, where the actual movement is interstate, do not affect either the power of Congress or the jurisdiction of the agencies which Congress has established.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.



The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

The functions of a label are not only to advise the ultimate purchaser, but also to furnish the evidence of compliance or non-compliance with the Act by the shipper.

Section 201 (k), Federal Food, Drug, and Cosmetic Act.

Seizure proceedings were instituted against drugs transported in interstate commerce to another in bulk for repacking and labeling, based on the failure of the label to contain the names of the active ingredients as required by Section 502 (e). The regulations issued under Section 503 (a), requiring a written agreement containing specifications, did not go beyond the statute.

Sections 201 (k), 304 (a), 502 (e), 503 (a), Federal Food, Drug, and Cosmetic Act.

To construe Section 503 (a) as to require regulations flatly exempting bulk shipments of drugs from the labeling provision would read an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act.

Section 503 (a), Federal Food, Drug, and Cosmetic Act.

Regard for the remedial purposes of the Act should cause it to be construed liberally.

Title, Federal Food, Drug, and Cosmetic Act.

Had Congress intended, by Section 503 (a), an outright exemption of bulk shipments from the labeling requirements of the Act without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption.

Section 503 (a), Federal Food, Drug, and Cosmetic Act.

Regulation (a)(1) of the regulations issued under Section 503 (a) pertains to a case where the repacker and the person shipping the article are the same person with plants in different states. The regulation does not exempt a repacker who obtains the goods in commerce through a vendor who sells the goods to it.

Sections 502 (e), 503 (a), Federal Food, Drug, and Cosmetic Act.

Herbert S. Avery, Boston, Mass.; Hugh D. McLellan, Boston, Mass.; Clinton Robb, Washington, D. C.; for appellants.

Alfred G. Malagodi, Assistant U. S. Attorney, Boston, Mass.; Edmund J. Brandon, U. S. Attorney, Boston, Mass.; for appellee.

Before MAHONEY and WOODBURY, Circuit Judges, and PETERS, District Judge.

### Opinion of the Court

#### [Facts of Case]

MAHONEY, Circuit Judge: This is a libel for the condemnation of certain drugs alleged to have been misbranded in violation of the Act of Congress of June, 1938, c. 675, 52 Stat. 1040, 21 U.S.C. §§ 301-392, known as the Federal Food, Drug, and Cosmetic Act. The drugs were manufactured in Buffalo, New York, by The Arner Co., Inc., for Paul Case of Brockton, Massa-

chusetts, under a special formula owned by Case and were shipped f.o.b. from Buffalo by Arner to Case in Brockton where they were seized on the premises of the latter while in the bulk package in which they had been shipped. The package, a drum of about 40,000 tablets, was labeled "Special Formula Tablets No. 2—The product contained herein must be packaged and labeled at point of destination before sale." The drugs were to be repackaged by Case for



the retail trade. The libel alleged that the drugs were misbranded in that the label did not contain the required names of the active ingredients of the preparation and contained no statement of warning and directions. The appellants denied that the drugs were misbranded and asserted that they were exempt from the labeling requirements of the Act as they were in bulk package, not retail packages and not intended for sale until repackaged and labeled. Paul Case, in his answer, asserts ownership of the goods. The Arner Company asserts that it shipped the goods as agent for Case and that at the time of shipment it had in its possession a duly executed guarantee from Case that the drugs shipped would be packaged and labeled to conform to the law before sale to the consumer. It is agreed that the composition of said Special Formula Tablets No. 2 is as follows: sugar coated tablets containing sodium citrate, sodium bicarbonate and extract of a plant drug, such as cascara sagrada. The Arner Company is not the operator of the establishment where the tablets were to be labeled or repackaged. The Arner Company and Paul Case here appeal from the decree of forfeiture. They contend (1) that "labeling" as defined in the statute does not apply to containers of bulk shipments; (2) that regulation (a)(2) of § 503(a) (21 U.S.C. § 353) is invalid because it exceeds the limitations of the statutes; (3) that if said regulation is not invalid, it has been sufficiently complied with; (4) that the bulk package herein involved is especially exempted under regulation (a)(1) of § 503(a).

*[Pertinent Law Provisions]*

Section 301 (a) (21 U.S.C. § 331) prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." By § 502 (21 U.S.C. § 352) it is provided that a drug shall be deemed misbranded:

"(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the

name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidoprime, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein . . ."<sup>1</sup>

Section 201 (k) (21 U.S.C. § 321) in defining "label" provides:

"The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

*[Labeling Requirement Applies to Bulk Shipments]*

Contrary to appellants' contention, this section does not indicate that the labeling requirement applies only to retail packages and not to bulk shipments. That could not be the proper interpretation in view of § 503 (a) which directs the administrator to promulgate regulations exempting such shipments on certain conditions:

"The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirements of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment."

The first clause of § 201 (k)—"The term 'label' means a display of written, printed, of graphic matter upon the immediate container of any article"—thus must refer to an immediate container of an article shipped in bulk as well as the retail package and the second clause in referring specifically to retail packages must be an extension of labeling requirements and not a limitation. If § 201 (k) were not intended to apply to bulk shipments, § 503 (a) would be pur-

dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. . . ."

<sup>1</sup> Also pertinent to the libel is:

"(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be



poseless and meaningless. There would be no need to provide for the promulgation of regulations exempting bulk shipments from labeling requirements under designated conditions if the labeling requirement applied only to retail packages in the first place.

[*Knowlton Danderine Case*]

Appellants rely in large part on a case under the Food and Drugs Act of 1906, 34 Stat. 768, *United States v. Sixty-five Casks Liquid Extracts*, 170 Fed. 449 (N. D. W. Va. 1909) affirmed on appeal by memorandum decision in *United States v. Knowlton Danderine Co.*, 175 Fed. 1022 (C. C. A. 4th, 1910). They contend (1) that that case was cited with approval in *Hipolite Egg Co. v. United States*, 220 U. S. 45 (1911), and (2) that it is squarely in point with the case at bar. The *Danderine* case was unsuccessfully relied on by the plaintiff in error in the *Hipolite Egg* case. The Supreme Court set forth that case as follows, pp. 52, 53:

"The articles involved in the first case were charged with having been misbranded and consisted of drugs in casks, which were shipped from Detroit, Michigan, to Wheeling, West Virginia, there to be received by the Knowlton Danderine Company in bulk in carload lots and manufactured into danderine, of which no sale was to be made until the casks should be emptied and the contents placed in properly marked bottles.

"It was contended that the articles, not having been shipped in the casks for the purpose of sale thus in bulk, but shipped to the owner from one State to another for the purpose of being bottled into small packages suitable for sale, and when so bottled to be labeled in compliance with the requirements of the act, were not transported for sale, and were therefore not subject to libel under § 10 of the act.

"The contention submitted to the court the construction of the statute. The court, however, based its decision upon the want of power in Congress to prohibit one from manufacturing a product in a State and removing it to another State 'for the purpose of personal use and not sale, or for use in connection with the manufacture of other articles, to be legally branded when so manufactured;' and concluded independently, or as construing the statute, that the Danderine Company, being the owner of the property, shipped it to itself and did not come within any of the prohibitions of the statute. The case was affirmed by the Circuit Court of Appeals,

175 Fed. 1022. The court, however, expressed no opinion as to the power of Congress. It decided that the facts did not exhibit a case within the purpose of the statute, saying: 'No attempt to evade the law, either directly or indirectly or by subterfuge, has been shown, it appearing that the manufacturer had simply transferred from one point to another the product he was manufacturing for the purpose of completing the preparation of the same for the market. Under the circumstances disclosed in this case, having in mind the object of the Congress in enacting the law involved, we do not think the liquid extracts proceeded against should be forfeited. In reaching this conclusion we do not find it necessary to consider other questions discussed by counsel and referred to in the opinion of the court.'"

Additional facts not stated by the Supreme Court were that Parke, Davis & Co., under a contract with the Danderine Company, compounded the product in accordance with a formula, a trade secret owned by the Danderine Company, and caused it to be shipped to that company. Whether it was a part of the agreed statement of facts, or whether it was a conclusion from the terms of the contract, Parke, Davis & Co. were considered by the circuit court to be agents of the Danderine Company and not independent contractors in the manufacturing of the product. We cannot conclude the same, nor was it so argued to us at the hearing, as to the Arner Company here. In the facts before us, insofar as the manufacturing of the drug is concerned, Arner Company cannot be said to be mere agents. They compounded the drug as independent contractors and title passed at some time to Paul Case.

[*Hipolite Egg Case*]

As was mentioned above, the Supreme Court refused to sustain the plaintiff in error's position in the *Hipolite Egg* case, and the plaintiff in error there relied on the *Knowlton Danderine* case. The facts in *Hipolite Egg Co. v. United States*, *supra*, p. 50, were these: the action was a libel under § 10 of the Act of 1906, 34 Stat. 768,

"\* \* \* against fifty cans of preserved whole eggs, which had been prepared by the Hipolite Egg Company of St. Louis, Missouri.

"The eggs before the shipment alleged in the libel were stored in a warehouse in St. Louis for about five months, during which time they were the property of Thomas & Clark, an Illinois corporation engaged in the bakery business at Peoria, Ill.



"Thomas & Clark procured the shipment of the eggs to themselves at Peoria, and upon the receipt of them placed the shipment in their storeroom in their bakery factory along with other bakery supplies. The eggs were intended for baking purposes, and were not intended for sale in the original, unbroken packages or otherwise, and were not so sold. The Hipolite Egg Company appeared as claimant of the eggs, intervened, filed an answer, and defended the case, but did not enter into a stipulation to pay costs.

"Upon the close of libellant's evidence, and again at the close of the case, counsel for the Egg Company moved the court to dismiss the libel on the ground that it appeared from the evidence that the court, as a Federal court, had no jurisdiction to proceed against or confiscate the eggs, because they were not shipped in interstate commerce for sale within the meaning of § 10 of the Food and Drugs Act, and for the further reason that the evidence showed that the shipment had passed out of interstate commerce before the seizure of the eggs, because it appeared that they had been delivered to Thomas & Clark and were not intended to be sold by them in the original packages or otherwise."

The decision of the Supreme Court affirming the decree of condemnation must be taken as in effect a disapproval of the doctrine of the *Danderine* case. As was said in *Strong, Cobb & Co. v. United States*, 103 F. (2d) 671, 673 (C. C. A. 6th, 1939):

"However, appellant maintains that under the doctrine of *United States v. Knowlton Danderine Co.*, 4 Cir., 175 F. 1022, there was in contemplation of law no shipment in interstate commerce under the Food and Drugs Act because the tablets were shipped in bulk, to be repackaged by the Scotch-Tone Company before retail distribution. The conclusive answer to appellant's contention is that the doctrine of the *Knowlton Danderine Co.* case has been in effect disapproved in *Hipolite Egg Co. v. United States*, 220 U. S. 45, 31 S. Ct. 364, 55 L. Ed. 364. In that case the *Knowlton Danderine* decision was relied on as supporting the proposition that Section 10 of the Food and Drugs Act, 21 U. S. C. A. § 14, does not apply to an article of food which has not been shipped for sale, but which has been shipped solely for use as raw material in the manufacture of some other product. The court, in discussing the proposition, states that the situations covered by the statute cannot be qualified 'by the purpose of the owner to be a sale' and holds that the contention of the Egg Company is untenable."

See also *Philadelphia Pickling Co. v. United States*, 202 F. 150, 151-2 (C. C. A. 3rd, 1913).

[*Passing of Title in State of Shipment  
Immaterial*]

The appellant Arner Company argues that title to the drugs passed to Paul Case within the state of origin for transportation and that Arner Company acted merely as agent for Case in shipping the goods in interstate commerce, hence the shipment is not within the Act. Such argument cannot avail the appellants. The passing of title in the state of origin for transportation does not take the case out of the Act. *Hipolite Egg Co. v. United States*, *supra*; *United States v. Tucker*, U. S. D. C. S. D. Ohio, April 8, 1911 (reported in *Decisions of Courts In Cases Under The Federal Food and Drugs Act* by Mastin G. White and Otis H. Gates, at page 248).

As was said in *Santa Cruz Fruit Packing Co. v. National Labor Relations Board*, 303 U. S. 453, 463 (1938):

"... sales to purchasers in another State are not withdrawn from federal control because the goods are delivered f.o.b. at stated points within the State of origin for transportation. See *Savage v. Jones*, 225 U. S. 501, 520; *Texas & N. O. R. Co. v. Sabine Tram Co.*, 227 U. S. 111, 114, 122; *Pennsylvania R. Co. v. Clark Bros. Coal Mining Co.*, 238 U. S. 456-468. A large part of the interstate commerce of the country is conducted upon that basis and the arrangements that are made between seller and purchaser with respect to the place of taking title to the commodity, or as to the payment of freight, where the actual movement is interstate, do not affect either the power of Congress or the jurisdiction of the agencies which Congress has established ..."

"The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution." *United States v. Dotterweich*, 320 U. S. 277 283 (1943).

[*Label Has Other Purposes in Addition  
to Advising Ultimate Consumer*]

The appellants argue that although *Hipolite Egg Co. v. United States*, *supra*, and *Strong, Cobb & Co. v. United States*, *supra*, were cases holding bulk shipments within the earlier Act, those cases involved adulterated goods which, of course, would be harmful to the ultimate consumer. Since such consumer never will see the label on the bulk package, the argument runs, there



is no protection to him in requiring such label and hence nothing in such a requirement facilitates the purposes of the Act.<sup>2</sup> The argument is based on the maxim that where the reason ceases (protection of consumer) the rule also ceases. The fallacy in this line of reasoning lies in misconception of the functions of the label. In addition to advising the ultimate consumer, there are other purposes of a label:

"The label upon the unsold article is in the one case the evidence of the shipper that he has complied with the act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the Federal authorities depend to reach and punish the shipper and to condemn the goods. If truly labeled within the meaning of the act his goods are immune from seizure by Federal authority; if the label is false or misleading within the terms of the law the goods may be seized and condemned. In other words the label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress." *McDermitt v. Wisconsin*, 228 U. S. 115, 132-133 (1913).

If adulterated bulk shipments are within the purview of the acts as established by the *Hipolite Egg and Strong, Cobb & Co.* cases, the requirement of labeling of bulk goods facilitates the detection and proof of such adulteration. Of course, enforcement of a labeling requirement could not be ef-

fective if the failure to meet the requirement were prosecuted only in the comparatively rare instances where the goods actually were adulterated.

Another facet of the same argument is appellants' contention that since Paul Case supplied the formula for the drugs he knew what they were to contain and therefore any label indicating the contents would be superfluous. This argument overlooks the aforementioned functions of a label. If the drugs sent out by the Arner Company were of less strength than called for by the order, Paul Case might not detect this and might repack them in retail containers, misbranding them because the Arner Company had not properly filled his order, and the ultimate consumer would be getting a product which was adulterated within the meaning of the Act. If the bulk shipment were labeled, the Food and Drug administrators would be aided in detecting the adulteration since they could sample the bulk shipment and compare it with the label. In this way the administration of the Act would be facilitated. Adulteration could be detected in the early bulk stage before it ever got into retail channels.

[Regulations Exempting Bulk Shipments  
from Labeling Requirement]

We turn now to consideration of § 503 (a) which provides for regulations exempting bulk shipments from the labeling requirement:<sup>3</sup>

<sup>2</sup> Since the regulations provided for by the Act exempt bulk goods from the labeling requirement on condition that certain information otherwise required on the label is set forth in an agreement, this argument would be more properly addressed to those regulations hereinafter considered.

<sup>3</sup> Sen. Rep. No. 493, 73rd Cong., 2d Sess., 1934, p. 9, accompanying S. 2800, one of the bills leading to enactment of the present law declared: "Par. (c) authorizes the exemption from any labeling or packaging requirement of the bill articles which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where they are originally processed or packed, on condition that the articles conform to the provisions of the bill at the time they leave the processing, labeling or repacking establishment. This exemption is necessary to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch can-

neries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers."

In House Report No. 2139 (75th Cong., 3rd Sess., 1938) the following comment on section 405(2) of the bill in relation to exemption of labeling with respect to food appears (p. 6):

"Section 405 authorizes exemptions from the labeling requirements of the act which are not provided by the present law but which have been permitted by administrative regulation. There is no necessity for labeling of any kind on most of the types of open containers of fresh fruits and vegetables. In certain cases there is a very real need for the exemption of canned food and other food from labeling. For example, most of the salmon packed in Alaska is shipped unlabeled to Seattle, Portland, and San Francisco, and from these points distributed under appropriate label. The exemptions will apply only where the interests of consumers will not be jeopardized."



"Sec. 353 (a). The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon the removal from such processing, labeling, or repacking establishment."

The pertinent regulation promulgated under this section provides:

"Regulation. [§ 2.107] (a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if—

"(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

"(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all

such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them."<sup>4</sup>

The appellants contend that the Administrator went beyond the statute in requiring a written agreement containing specifications. Their contention is that § 503 (a) requires regulations flatly exempting such bulk shipments from the labeling provision and providing no safeguarding conditions to such exemption. To so construe the section would "read(s) an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act". *United States v. Dotterweich*, 320 U. S. 277 (1943). The Supreme Court thus clearly indicated in the *Dotterweich* case what must be our guide in construing the Act. As Mr. Justice Frankfurter said:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words: See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128. \* \* \* Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that

<sup>4</sup> The remainder of this regulation provides:

"(b) An exemption of a shipment or other delivery of a drug or device under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed. . . ."

"(d) An exemption of a shipment or other delivery of a drug or device under clause (2) of paragraph (a) of this regulation shall expire—

"(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

"(2) upon the refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause."



the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906.' (H. Rep. No. 2139, 75th Cong., 3rd Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws', but on the contrary 'it must strengthen and extend the law's protection of the consumer.' (S. Rep. No. 152, 75th Cong. 1st Sess., p. 1)."

Section 503 (a) does not state the exemption. "It authorizes the formulation of the exemption by regulations. Therefore, unless contrary to law, arbitrary, or unreasonable, the terms of the exemption can be prescribed in the discretion of the administration". See Hoge: *An Appraisal of the New Drug and Cosmetic Legislation*, 6 Law and Contemporary Problems 116. Had Congress intended an outright exemption of bulk shipments from the labeling requirement without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption. The agreement containing specifications for the labeling of the drugs as provided in regulation (a) (2) serves the same purposes of facilitating the enforcement of the Act as was indicated by the Supreme Court in *McDermott v. Wisconsin*, *supra*, to be the purpose served by a label on a retail article before the article is sold. Applied to a situation like the case at bar it would aid in the detection and proof of adulteration in the shipment from the manufacturer to the

proprietor of the formula. Cf. *Strong, Cobb & Co., Inc. v. United States*, *supra*. There is no hinderance to honest business in this requirement. The instrument<sup>5</sup> which is here purported to be such an agreement is neither signed by the shipper nor does it contain any specifications for the labeling as required by the regulation (a) (2). Obviously such an instrument does not serve the useful function indicated above and was intended for some purpose entirely foreign to the regulation.

Regulation (a) (1) is not applicable to this case. It pertains to a case where the repacker and the person shipping the article to be repacked are one and the same person with plants in different states. See Toulmin, *Law of Food, Drugs and Cosmetics* (1942) p. 322, § 173. There is no danger in such a case of the repacker unwittingly passing on adulterated drugs to the ultimate consumer. The regulation does not exempt a repacker who introduces the goods into commerce through an "agent" designated for that purpose, which "agent" was the vendor of the goods. This "agency" of the Arner Company to ship the goods can no more bring the appellants within regulation (a) (1) than can it avoid the scope of interstate commerce as indicated by the cases cited in the earlier part of this opinion.

[Decree of Forfeiture Affirmed]

The decree of the District Court is affirmed.

<sup>5</sup>

"Paul Case,

Sole Distributor Case Combination New Improved Method for 'Rheumatic' Pains,  
33 Hamilton St., Brockton, Mass.

April 28, 1939, Brockton, Massachusetts.

To The Arner Company, Inc., Pharmaceutical Chemists, Buffalo, New York.

I, the undersigned, Paul Case, whose address is 33 Hamilton St., Brockton, State of Massachusetts, hereby guarantee the Arner Company,

Inc., of Buffalo, New York, that each shipment or other delivery hereinafter made of the drugs known or designed as my formula No. 1 and formula No. 2 is not adulterated or misbranded, as of the date of such shipment or delivery, within the meaning of the Federal Food, Drug and Cosmetics Act, and is not an article which may not under the provisions of sec. 505 of the act be introduced into commerce.

(signed) Paul Case, Owner."



*U. S. v. 62 Packages of Marmola Prescription Tablets et al.*

# UNITED STATES v. 62 PACKAGES, MORE OR LESS, OF MARMOLA PRESCRIPTION TABLETS AND RALADAM COMPANY

United States Circuit Court of Appeals for the Seventh Circuit. No. 8357.

May 4, 1944. 142 F. 2d 107.

Certiorari denied, *Raladam Co. v. United States*, 323 U. S. 731 (1944).

Affirming 48 F. Supp. 878. See page 34.

The finding of a trial court should not be set aside unless clearly against the weight of the evidence.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

In a seizure action against "Marmola," a reducing preparation containing thyroid, the evidence justified the conclusion reached by the trial court that Section 502 (j) of the Act had been violated because the product, when used as recommended in the labeling, was dangerous to health.

Sections 304 (a), 502 (j), Federal Food, Drug, and Cosmetic Act.

The fact that some users might be able to tolerate quantities greater than those recommended on the label did not militate against the conclusion reached by the trial court that the product was dangerous to health when used as recommended in its label, and therefore violated Section 502 (j), for the section does not require that the drug be dangerous to the health of all who take it in the dosage and for the duration prescribed or recommended.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

Since the judgment was required to be sustained for a violation of Section 502 (j), it was unnecessary to discuss findings of the trial court that "Marmola" tablets were misbranded under Section 502 (a) in that they were falsely represented to be a safe remedy for obesity, and under Section 201 (n) in that the label did not reveal material facts as to the possible consequences of the use of the tablets.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The legislative history of the Act discloses that Congress had no intent to deprive individuals of the right of self-medication; but the decision of the lower court adverse to "Marmola" tablets deprived no one of that right; it merely determined that the tablets were dangerous to the public health when used as prescribed by the claimant.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

John J. Boyle, Alvin M. Loverud, for libelant-appellee.

Rockwell T. Gust, David A. Howell, W. H. Dougherty, for respondent-claimant-appellant.

Before MAJOR, MINTON, Circuit Judges, and LINDLEY, District Judge.

## [Reversal of Condemnation Sought]

LINDLEY, District Judge: Claimant seeks to reverse a judgment condemning "Marmola" drug tablets entered in a proceeding under the Federal Food, Drug, and Cosmetic Act (c. 675, 52 Stat. 1040; Title 21 U. S. C. A., sec. 301 *et seq.*). The essential averments of the libel were that the tablets were misbranded in that (1) when used as

prescribed they are dangerous to health; (2) they are falsely represented to be a safe and appropriate remedy for obesity, and, (3) the instructions for use fail to reveal facts material with respect to the consequences which may arise upon the use of the drug as prescribed, thus violating Sections 502 (a), 502 (j) and 201 (n) of the Act<sup>1</sup>.

<sup>1</sup> Section 502: "A drug or device shall be deemed to be misbranded: (a) If its labeling is false or misleading in any particular."

Section 502: "A drug or device shall be deemed to be misbranded: (j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

Section 201: "For the purposes of this Act—(n). If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account among other things not only representations made or sug-

(Footnote 1 is continued on page 108.)



## [Labeling]

The Government complained of the printed matter on the packages and in the circulars accompanying them. The directions on the box read: "Take one tablet before each meal and at bedtime with enough water to swallow easily or as directed by a physician. Marmola is recommended only as a treatment for adult fat persons whose excess fatness is caused by hypothyroidism with accompanying subnormal metabolic rates but who are otherwise normal and healthy. Marmola should not be taken by persons suffering from any abnormal condition except abnormal excess fat caused as above stated. We make no diagnosis as that is the function of your physician who must be consulted for that purpose. Marmola is not recommended for children. Before taking be sure to read the enclosed circular."

The instructions in the circular are more detailed; only the part which it is necessary to consider is quoted: "\* \* \* Marmola is not sold as a cure-all. It is intended for use only by obese (obesity is the term used by the medical profession for an excessive development of fat throughout the body) persons who are otherwise normal and healthy and whose obesity is caused by hypothyroidism with accompanying subnormal metabolism, and our statements and representations made herein or otherwise are strictly limited to this treatment under these conditions and according to the dosage as recommended. We do not make any diagnosis as that is the function of your physician, who must be consulted for that purpose. Marmola should not be taken by persons suffering from any abnormal condition except obesity (abnormal excess fat) caused as above stated."

## "Important Directions

## "First

"Take one Marmola tablet before each meal and one at bedtime—four a day. Do this regularly.

## "Second

"For best results we recommend that Marmola be used as directed over a period of sixty to ninety days—if needed that long.

\* \* \*

"\* \* \* No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unplea-

sant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. Such a condition can not always be predicted either by physicians or others. If any unpleasant effects are experienced stop taking Marmola until they disappear, then resume taking one-half of the former dosage or consult a physician."

## "Suggestions.

"\* \* \* The idea that excess fat is always due solely to laziness or gluttony has been dissipated by science. One may be active and eat moderately and still grow fat, if a deficiency exists which causes too much food to be converted into fat instead of energy.

"Marmola is a time-tested aid to correct this basic cause of the abnormal excessive fat accumulated by reason of the deficiency it is designed to correct."

## "When to Stop

"\* \* \* But you are the best judge of the weight at which you feel the best and are most efficient. Stop taking Marmola as soon as you lose your abnormal excess weight. If, later, you should start to gain again take more Marmola tablets until conditions are corrected."

"\* \* \* Consult your physician if any unusual circumstances or conditions arise."

"Your doctor, of course, is opposed to self-medication. He may prefer to write his own prescription for some special case, but the Marmola prescription has been developed by over 30 years of experience and its efficiency has been tested by the sale of over 20,000,000 boxes throughout the world."

## [Question Before Court]

Our essential question is whether the evidence is such as to justify us in saying as a matter of law that the District Court's finding that Section 502 (j) of the Act has been violated because Marmola tablets, when used in the dosage and with the frequency and for the duration prescribed, recommended or suggested in their labeling, are dangerous to health is erroneous. Obviously the finding should not be set aside unless clearly against the weight of the evidence. Rule 52 (a) Rules of Civil Procedure, 28 U. S. C. A. following Section 723: *Sauder v. Dittmer* (CCA 10), 118 F. 2d 524; *United States v. State Street Trust Co.*, (CCA 1), 124 F. 2d 948; *Super Mold Cor-*

gested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result

from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."



*U. S. v. 62 Packages of Marmola Prescription Tablets et al.*

*poration of California v. Bacon*, (CCA 9), 130 F. 2d 860; *Stork v. Townsend*, (CCA 6), 132 F. 2d 859; *Wertz v. National City of Evansville, Ind.*, (CCA 7), 115 F. 2d 65, cert. den. 311 U. S. 675.

[*Hypothyroidism and Metabolism*]

Claimant has sold this medical concoction for more than thirty years as a reducing aid for persons whose obesity is supposed to be caused by hypothyroidism and have an accompanying subnormal metabolism. "Hypothyroidism," resulting from under-functioning of the thyroid gland, is accompanied by a subnormal metabolic rate and such symptoms as dryness of the skin, scarcity of hair and eyebrows, sluggishness of physical and mental reactions, decreased appetite, slower pulse rate and characteristic changes in the composition of the blood, and, in advanced stages, by a puffy and swollen appearance of the face and other parts of the body due, not to increased fatty tissue but to mucoid fluid deposited beneath the skin. "Metabolism" denotes the sum total of all processes of the human body by which food is transformed into chemicals in turn absorbed into the blood stream and lymphatic system for the purpose of so nourishing the body that it can continue to function. In other words, it is the aggregate of all processes whereby food is digested, heat and energy created, the body built up or repaired and waste matter excreted. By examination of the rates at which normal persons give off heat, scientists have established the normal rate of metabolism from which, experience has revealed, most persons deviate by not more than 10 per cent. To enjoy good health, one's body must maintain a proper balance of essential chemicals; the thyroid gland is the primary agency in achievement of this end. Excess of the thyroid hormone in the blood stream results in hyperthyroidism and too little in hypothyroidism.

[*Desiccated Thyroid Ingredient*]

The only ingredient of the condemned drug with which the proceeding was concerned is the desiccated thyroid included in the formula. This is derived from the thyroid glands of hogs and sheep, and has the same effect upon one's physical make-up as the hormones produced by a human gland. The potency of desiccated thyroid is roughly proportional to its iodine content. The product here contains approximately 0.3% of organic iodine and thus possesses one and one-half times the potency of that made in accord with the standard of the U. S. Pharmacopoeia.

[*Evidence*]

Qualified authorities and specialists in medicine, chemistry and nutrition, supplied testimony, somewhat in conflict, relating to the cause and "cure" for obesity, hypothyroidism and hyperthyroidism and to metabolism, as well as proof of the effect of thyroxin upon persons suffering from Graves' Disease, heart disease, amenorrhea and psychoneuroses. The evidence discloses that an overdosage of desiccated thyroid produces hyperthyroidism. Indeed, as to this there can be no question, since such medication supplies an excess of the hormone. The record also reveals that medical men are in agreement that one person's tolerance for the drug may be a great deal less than another's. Claimant recognizes this, too, since, in the circular it warns,

"No food, drug or other substance which has any physiological effect may be taken internally or applied externally without the possibility of unpleasant or harmful results in some persons if they happen to be constituted so that they do not tolerate the food or other substance. \* \* \* If any unpleasant effects are experienced stop taking Marmola until they disappear \* \* \*."

Medical witnesses testified as to further effects of overdosage, such as increased metabolism of the patient, injuriously affecting the functioning of the endocrine glands, kidneys and liver; impairment of bodily functions because of the extra burden placed upon human organs; symptoms which can not be distinguished from those peculiar to hyperthyroidism, such as rapid heart, heart pains, nervous and emotional instability, nausea, menstrual disturbances; serious aggravations which result in persons who consider themselves normal and healthy, but are actually subject to such latent diseases as heart disease, diabetes, tuberculosis, when they use desiccated thyroid. Indeed, their testimony is largely to the effect that a daily dosage of two grains a day is dangerous to health. Lay witnesses gave vivid reports of the effect of the tablets upon their health. Weakness, heart palpitations, amenorrhea, emotional nervous states, and domestic difficulties were described as aftermaths of the use of the tablets. One witness reduced her weight from 165 pounds to 95 pounds, then ceased to take the tablets, but continued to lose until she weighed only 50 pounds. The testimony of toxic effect of desiccated thyroid in prescribed Marmola dosage was conflicting. Clinical tests by Dr. Killian and Dr.



Allen, in which the amount of the hormone were greatly increased, were said to reveal no harmful and lasting results.

[*Conclusion of Trial Court as to  
 Dangerousness Justified*]

We think the evidence such as to justify only the conclusion reached by the trial court. We certainly are not justified in saying that the finding is erroneous as a matter of law. Admittedly, taking four tablets a day, is not dangerous to the health of all users, since tolerance for the drug varies; but the experience of various witnesses, all of whom took tablets according to the directions on the label, as well as the testimony of a number of medical experts, inevitably impel one to the finding that use of the tablets as prescribed is dangerous to the health of the public. The fact that some users may be able to tolerate greater quantities, as the experiments conducted by Dr. Killian and Dr. Allen tend to show, does not militate against the conclusions, for Section 502 (j) does not require that the drug must be dangerous to the health of all who take it in the dosage and for the duration prescribed or recommended. It developed upon the trial court to determine only whether it was proved that the drug is dangerous to the public health at large if used as recommended by its vendors. *U. S. v. Lexington Mill & Elevator Co.*, 232 U. S. 399.

[*False and Misleading Labeling; Failure To  
 Reveal Material Facts*]

The trial court further found the tablets subject to condemnation under Section 502 (a), in that they were misbranded because

they were falsely represented to be a safe and appropriate remedy for obesity, when in fact they are not, for the reason that obesity is not caused by the lack of any substance which Marmola supplies; and, under Section 201 (n), in that the labels did not reveal facts material with respect to possible consequences of use of the tablets under the conditions prescribed, since the instruction to discontinue use of the tablets upon appearance of "unpleasant effects" does not prevent the occurrence of more serious symptoms as a result of the hyperthyroidic condition previously precipitated. It is unnecessary to discuss these findings, since the judgment must be sustained for violation of Section 502 (j). For the same reason, we find it unnecessary to consider other contentions regarding Sections 502 (a) and 201 (n).

[*Right of Self-Medication Not Affected*]

Claimant makes much of the proposition that the legislative history of the Federal Food, Drug, & Cosmetic Act discloses that Congress had no intent to deprive individuals of the right of self-medication. This we think beyond the point, for the decision of the lower court deprives no one of this right. It merely determines that Marmola tablets are dangerous to the public health when used in the dosage and with the frequency prescribed by claimant. What would be a non-deleterious prescription was not agreed upon by the experts and was not within the province of the court to decide.

[*Condemnation Affirmed*]

The judgment is affirmed.

**UNITED STATES v. 1851 CARTONS, MORE OR LESS, EACH  
 CONTAINING 15 POUNDS OF FROZEN WHITING,  
 LABELED IN PART "H & G FAMOUS BOOTH  
 SEA FOODS WHITING FROSTED  
 FISH"**

United States District Court for the District of Colorado. No. 11605. Filed  
 May 22, 1944. 55 F. Supp. 343.

Reversed, 146 F. 2d 760. See page 134.

On a motion to dismiss a libel at the end of the Government's case, the court is required to consider the Government's evidence only, giving it full value as uncontradicted.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

"Decomposed" means more than the beginning of decomposition, it means a state of decomposition, and the statute must be given a reasonable interpretation to carry out the legislative policy or intent.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.



*U. S. v. 1851 Cartons of Frozen Whiting etc.*

In a seizure action against fish, since the Government had proved that less than 6 per cent of the entire shipment was decomposed and there was no evidence that even the bad fish was sufficiently decomposed to violate the object of the statute, and since there was a suspicion as to the efficiency of the organoleptic test alone as justifying the condemnation of the entire shipment, the libel would be dismissed.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Bart W. O'Hara, Assistant U. S. Attorney, Denver, Colo. (Vincent A. Kleinfeld, of counsel), for plaintiff.

Hyman D. Landy, Denver, Colo., for defendant.

**Memorandum Opinion on Defendant-  
Claimant's Motion to Dismiss  
the Libel**

*[Prior Proceedings]*

J. FOSTER SYMES, District Judge: The defendant-claimant at the end of the Government's case moved to dismiss the libel on the ground that the Government's evidence does not sustain the charge.

After considerable argument the court granted the motion, stating its reasons, upon the condition that the claimant give bond that in the selling or disposition of any of this fish they give to the retailers written notice calling attention to the fact there had been found in the shipment an occasional bad fish, and the retailer before selling or delivering it to any customer should warn the purchaser to examine it himself. This was agreed to by both sides in open court, and a written notice was duly prepared and agreed to, consisting of a rubber stamp containing such a notice to be affixed to every carton or box as it left the possession of the claimant.

Later the Government, for good and sufficient reasons I presume, withdrew its consent to this arrangement and has asked for a clear decision on the merits. The court therefore withdraws the above memorandum and substitutes the following in passing upon the motion.

*[Adulteration Charged]*

The charge is that contrary to § 331, Tit. 21, U. S. C. A., the defendant introduced 1851 cartons, more or less, each containing 15 pounds of frozen whiting (fish), into interstate commerce by transporting it from Provincetown, Massachusetts to Denver, Colorado. That said article of food was adulterated within the meaning of § 342 (a) (3), Tit. 21, U. S. C. A., in that it consisted "in whole or in part of a decomposed substance."

Said § 342, Tit. 21, U. S. C. A. (a) (3), says, "a food shall be deemed to be adulterated" as the libel charges (3),

"If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

The Government has left out of its charge the last part of the subsection as follows, to wit, the words

"or if it is otherwise unfit for food."

*[Only Government's Evidence Considered]*

On this motion we are required to consider the Government's evidence only giving it full value as uncontradicted.

*[Testimony of Government's Experts]*

Our decision of this motion necessarily depends upon the testimony of the Government experts. The chief Government witness, Dr. Lewis Chernoff, is a graduate chemist employed for many years by the U. S. Food and Drugs Administration in Denver. Dr. Chernoff has appeared in this court many times in similar cases and we entertain a very favorable opinion of his ability. He testified he has examined fish products for many years, and on November 9th and 10th, 1943, examined 26 boxes taken as samples from this shipment, seized by the Government while in a cold storage plant in Denver, and taken to Dr. Chernoff's office. The fish when delivered to him were in hard, frozen blocks. He opened the cartons, put the fish in trays permitting them to thaw out overnight. Next day he examined each fish separately by cutting or slitting it down the back and smelling. This is known as the organoleptic test.

In many of the boxes he did not find any decomposed or bad fish at all. Out of a total of 1119 fish he found 55 or 4.9% decomposed. By decomposed he meant rotten, unfit for human consumption. His test—the only one he made—was his sense of smell, the odor being very offensive. The following questions and answers are informative:

"Q. If someone had eaten them what effect would it have had?

"A. I don't know. If they were cooked they probably might be all right.



"Q. What?

"A. If they were cooked and eaten they might be all right. They might cause illness. I have no idea."

He said the balance of the fish outside of the 55 were all right.

On cross-examination he testified that whiting was a salt water fish and when received were headless and gutted. That he made a personal examination of every one of the 1119 fish. That of those he examined the skin appeared to be normal and firm. That he made no notes on the physical condition of the fish. He did not make a bacteriological examination or chemical test, but simply organoleptic; that is a test by the senses of smell, sight, touch and taste. He did not make an indol test—indol being one of the by-products of decomposition of protein products and might determine decomposition. His test consisted simply of subjecting the 1119 fish to his sense of smell. Further, to sum up, of the 1119 fish so examined 55 smelled bad or putrid, and the balance were edible.

On being recalled the witness testified he examined another 18 boxes of this same shipment on January 25th. Like the other examination they were frozen. He opened the boxes and placed the fish on pans allowing them to thaw overnight. He examined them the next morning. That out of the total of 768 fish 48 were unfit for food, or 6.2% by count. The only test he made was the organoleptic; that is he judged them solely by the smell.

At the trial of the case—and at the request of counsel for both sides—additional samples of the whiting were brought into a room adjoining the court and opened up and examined by Dr. Chernoff and the court. The results of this examination are shown in Govt. Ex. A, signed by Mr. Williams, defendant's expert Mr. Vincent, head of the Food and Drug Division office in Denver and Dr. Chernoff. Four hundred and eleven fish selected at random were examined in the presence of the court and the average per cent of bad fish found therein by Dr. Chernoff was 3.6%; that is to say 15 out of 411 fish, it was agreed, were unfit, showing signs of decomposition. The court found these upon personal examination to have a bad, disagreeable, putrid odor.

[*Question in Case*]

While the sole question in the case, under the pleadings, is whether the fish consisted wholly or in part of a decomposed sub-

stance, the over-all question of course is whether they were fit for human consumption.

[*Percentage of Decomposition; Danger of Poisoning*]

It will be observed from Dr. Chernoff's testimony that the number of decomposed fish in the first exhibit unfit for human consumption was less than 5%, and of the second lot examined in January was a little over 6%. No witness qualified to or attempted to state what the effect of eating any of these decomposed fish would have upon the consumer. Dr. Chernoff did testify that the housewife would, in processing these fish before serving them, have ample opportunity to detect any bad odor. He said the cooking they would be subjected to might in most instances eliminate any danger of food poisoning. Furthermore, it would seem that the effect on the human system if consumed as food would depend largely upon a bacteriological test, which in this case was not made.

[*Commercial Creamery Case*]

*U. S. v. Commercial Creamery Co.*, 43 Fed. Supp. 714, involved frozen eggs. The testimony of the Government was that of three witnesses who inspected the eggs sought to be condemned. They used the organoleptic test only, and while the case was a criminal one where the Government's allegations must be proved beyond a reasonable doubt, the court on such testimony dismissed the action, recognizing that the organoleptic test was justified only because it was quicker and, as the Government inspector testified, permitted more territorial coverage than could be obtained by the combined use of this method with any of the other three. The court noted that chemists had for years been seeking more efficient and rigid methods for determining decomposition of eggs, citing authorities, and observed that it was difficult for the court to believe that if the organoleptic test is as efficient as the Government witnesses said it was, that such complete and consistent efforts were being made by the chemists to acquire rapidity in their processes. And further stated that what is true of the chemists is also true of the bacteriologists, and stated it doubted whether the American Public Health Association would have interested itself to the extent that it has in bacteriological studies if the Government's contention as to the scientific efficiency of the organoleptic method were correct.



*[Percentage of Decomposition Found in Test in Court]*

In the case at bar the organoleptic test made by the Government's chemist in the presence of the court was that less than 4% of the fish in question were decomposed, and according to Dr. Chernoff this might be very greatly reduced by the processing that the fish would undergo in the house before being consumed.

*[Other Cases]*

In *U. S. v. Two Hundred Cases of Catsup*, 211 Fed. 780, it says, p. 782:

"\* \* \* there is no fixed standard by which it can be determined when a product has reached such a state of decomposition as to 'consist in whole or in part of filthy, decomposed, or putrid vegetable substance,' \* \* \* I infer from the testimony of the experts that it would be difficult, if not impossible, to fix any arbitrary standard by which the question could be determined, as it depends upon so many contingencies. In any event, no such standard has been fixed, in the absence of which each case must be determined on its own facts."

And in *Andersen v. U. S.*, 284 Fed. 542, it is said, p. 545:

"It appeared from the cross-examination of the government witnesses that they have heretofore suffered canned salmon containing a small percentage of filthy, decomposed, or putrid matter to pass in interstate commerce unchallenged, but there is no room for controversy over percentages under the statute itself, for it excludes all. Of course, where the entire product is not inspected or tested, the proof must go far enough to satisfy the court or jury that the adulteration extends to the whole product sought to be condemned."

*[No Authority for Condemning Entire Shipment Because of Small Percentage of Decomposition]*

I find no case that holds an entire shipment, such as the one at bar, can be condemned merely upon a finding that a percentage as small as the evidence here is decomposed, especially where there is no charge or evidence that the fish is unfit for food.

*[Canned Salmon Case]*

In *U. S. v. Two Hundred Cases, More or Less, of Canned Salmon*, 289 Fed. 157, Judge Hutcheson—then a District Judge—discussed this whole question and refused to follow the *Andersen* case, stating that while proof that the contents of 20% of cans in a

shipment were adulterated with nothing more, might authorize the inference the whole product was bad, and therefore support a condemnation of the lot where the same proof which establishes the adulteration of one-fifth establishes the lack of adulteration of the balance, the Government must fail, except as to the cans identified as adulterated. The court analyzed the testimony—which was about the same as in the case at bar—and stated the Government evidence proving part bad, and relied on for the inference that all was bad, proved just as conclusively that part of it was not bad within the meaning of the statute; that if the Government depended for its condemnation upon subdivision 6 of § 7 of the Act, in accordance with the general rule of law that the burden is upon the Government to prove its case, the Government would have to be cast in this suit, or would have to take the alternative of examining and testing every can of the shipment. That view is applicable to our situation. The testimony of Dr. Chernoff proves that except for the number of bad fish found, the balance of the shipment which he examined was all right and fit for human consumption. See also *Baker v. Latses* (Utah) 206 Pac. 553.

*[Corpus Juris References]*

C. J. S. Vol. 36 § 16, p. 1076:

"Statutes and ordinances intended to prevent the manufacture or sale of food or food products that are unwholesome or unfit for human consumption will be enforced in accordance with their proper construction. \* \* \* or by reason of their decay," [*Commonwealth v. Prince*, 89 N. E. 1047] "The statutes are not intended to regulate tastes or appetites, and the courts will not deem an article of food unwholesome merely because it is unpalatable to many, or even most, persons." [*McNeill & Higgins Co. v. Martin*, 107 So. 299]. "Furthermore, an article of food is not unwholesome within such a statute, merely because it is unwholesome to a particular individual or to normal persons under abnormal conditions; it must have such qualities that normal persons generally, in a normal condition, would be adversely affected by its consumption. It has been said that the condition of a product in the hands of a consumer is the place and time to test its fitness for food"; [*U. S. v. Four Hundred and Forty-Three Cans of Frozen Egg Product*, 193 Fed. 589].

And according to § 15, p. 1073:

"\* \* \* an article of food shall be deemed adulterated \* \* \* if it contains any



poisonous or deleterious substance which may render it injurious to health," [*U. S. v. 1232 Cases American Beauty Brand Oysters*, 43 Fed. Supp. 749] "or contains any added substance or ingredient which is poisonous or injurious to the health, \* \* \* or consists in whole or in part of a filthy, decomposed, or putrid substance," [52 Fed. (2d) 476; 43 Fed. Supp. 714; 208 Fed. 419].

C. J. S. Vol. 36, Note 61, p. 1074:

"The word 'decomposed,' as used in such a statute" [referring to the Federal statute], "means more than the beginning of decomposition; it means a state of decomposition." See also 26 C. J. p. 762, Note 76; and 284 Fed. 542 (*infra*).

[*Andersen Case*]

In *Andersen v. U. S.* (*supra*), a food case, 408 cans of salmon were selected at random from 408 of 1974 cases. One hundred forty-four cans of the second lot were first analyzed and found to contain 28 putrid or tainted, and 18 stale cans, and 48 of the balance were later analyzed and found to contain eight putrid or tainted, and one stale can. The third lot of 192 cans contained 35 putrid or tainted, and 12 stale cans. That a putrid or tainted can was said to be one that contained rotten or decayed salmon with an offensive odor, while a stale can was disclosed as the beginning of decomposition, but not in so far advanced a stage as the putrid or tainted cans. The net result was that one-fifth of the product analyzed was putrid or tainted and one-fourth either putrid and tainted, or stale. It further appeared that decayed salmon was not injurious to health.

The claimant offered no testimony and upon its motion the court directed a verdict in its favor, which was reversed by the Court of Appeals, which said that decomposition begins when life ends, but meat and fish are not decomposed at that early

stage. Decomposed means more than the beginning of decomposition, it means a state of decomposition, and the statute must be given a reasonable interpretation to carry out the legislative policy or intent.

[*Commercial Creamery Case*]

In *U. S. v. Commercial Creamery Co.* (*supra*), it was held that the Federal Food, Drug, and Cosmetic Act is designed to prevent injury to the public health and the introduction into interstate commerce of foods which consist in whole or in part of any filthy, putrid or decomposed substance, and the intent of Congress was to exclude from interstate commerce impure and adulterated food, and to prevent facilities of commerce from being used to enable such articles to be transported to people who consume them. And it is in the light of such power exerted by Congress that the Act must be construed.

[*Percentage of Decomposition Small; Unfitness for Consumption Not Shown; Organoleptic Test under Suspicion*]

In conclusion: The Government's testimony proves that a very small percentage of the entire shipment (less than 6%), was decomposed and the balance (95% plus), was all right. There is no evidence that even the bad fish was sufficiently decomposed to violate the object of the statute, to wit, to prevent the introduction into interstate commerce of food unfit for human consumption. Further under the authorities (*supra*), the testimony, to say the least, throws considerable suspicion on the efficiency of the organoleptic test alone as justifying the condemnation of the entire shipment.

[*Libel Dismissed*]

The motion for a directed verdict is granted and the libel dismissed.



*U. S. v. 306 Cases "Sandford Tomato Catsup with Preservative"*

**UNITED STATES v. 306 CASES, MORE OR LESS, EACH CONTAINING 6 NO. 10 CANS OF AN ARTICLE LABELED IN PART "SANDFORD TOMATO CATSUP WITH PRESERVATIVE"**

United States District Court for the Eastern District of New York. M-698.

May 24, 1944. 55 F. Supp. 725.

Affirmed 148 F. 2d 71. See page 145.

The product under seizure conformed to the definition and standard of identity for tomato catsup except for the inclusion of benzoate of soda, the presence of which was revealed on the label and in the title of the product. To give recognition to the claimant's contention that the product was different from the standardized product would be to thwart the entire purpose of the legislation.

Sections 304 (a), 401, 403 (g), Federal Food, Drug, and Cosmetic Act.

The text and legislative history of the statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling.

Title, Federal Food, Drug, and Cosmetic Act.

It was not necessary to decide the Court's power to review the Administrator's refusal to permit benzoate of soda as an optional ingredient, for assuming the power, his decision was correct.

Sections 401, 403 (g), 701 (f), Federal Food, Drug, and Cosmetic Act.

If every food for which a standard has been prescribed would become an entirely different food by the addition of one ingredient, it would be a simple matter completely to evade and circumvent the purpose of food standards.

Sections 401, 403 (g), Federal Food, Drug, and Cosmetic Act.

The evidence clearly showed that the seized product purported to be tomato catsup and that it did not conform to the definition and standard of identity promulgated therefor.

Section 403 (g), Federal Food, Drug, and Cosmetic Act.

Harold M. Kennedy, U. S. Attorney; Morris K. Siegel, Assistant U. S. Attorney; for libelant.

Breed, Abbott & Morgan; Michael F. Markel of counsel; for claimant, Libby, McNeill & Libby.

*[Condemnation Sought; Interstate Commerce and Jurisdiction Conceded]*

MOSCOWITZ, District Judge: Libelant prays for a decree of this Court condemning approximately 306 cases of an article of food labeled in part "Sandford Tomato Catsup with Preservative." Claimant concedes that the article under seizure was shipped by it in interstate commerce to this district, and that it was seized by a Deputy United States Marshal within the jurisdiction of this Court.

*[Misbranding of Tomato Catsup Charged]*

The libel charges that the seized article is misbranded within the meaning of the

Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 343 (g) (1). If it is misbranded, it is subject to seizure and condemnation by authority of 21 U. S. C. 334. Under the applicable section of the Act, a food shall be deemed to be misbranded "if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless it conforms to such definition and standard. . . ." Acting pursuant to 21 U. S. C. 341 and 371, the Federal Security Administrator issued an order, effective January 1, 1940, promulgating a definition and standard of identity for tomato catsup (4 F. R. 3454), and subsequently refused to amend the prescribed



standard, upon the application of Cannery League of California, of which claimant was a member, so as to permit the addition of benzoate of soda as an optional ingredient (6 F. R. 209).

[*Claimant's Contentions*]

The product under seizure conforms in all respects to the definition and standard promulgated by the Administrator for tomato catsup, except that it contains in addition 1/10 of 1% of benzoate of soda. The label on the seized product reads: "Sandford Tomato Catsup with Preservative" (all in the same size type) "This product does not conform to the government standard for catsup. Contains 1/10 of 1% of benzoate of soda." Claimant contends (1) that it is not marketing tomato catsup, but an entirely separate and different product designated as "tomato catsup with preservative," for which it claims no standard has been promulgated and which it has truthfully labeled, and (2) that the Administrator's refusal to permit the addition of benzoate of soda as an optional ingredient had no reasonable basis in fact and that the standard is therefore void.

[*Label Declaration of Additional Ingredient No Defense*]

To give recognition to a distinction such as claimant asserts would be to thwart the entire purpose of the legislation herein sought to be enforced. The Congressional objective in authorizing the promulgation of standards for foods and requiring compliance therewith is stated in the statute to be to "promote honesty and fair dealing in the interest of consumers." Experience had shown that truthful labeling of a product was no protection to the bulk of the consuming public; if a product gave the appearance of being a certain food, the public assumed that it contained only those ingredients which were commonly associated with that food and the label was never consulted. Even a reference to the label might not enlighten a consumer on the nature of unfamiliar ingredients there set forth. To remedy this general situation, Congress authorized an administrative officer (originally the Secretary of Agriculture, whose functions in this respect were subsequently transferred to the Federal Security Administrator), either on his own initiative or upon application of interested persons, to determine what ingredients in a particular food would promote honesty and fair dealing in the interest of consumers. When

a standard has been promulgated for any food, any product which "purports to be" or "is represented as" that food must conform to the standard or it is misbranded and subject to condemnation. That an additional ingredient not mentioned in the standard is non-deleterious is immaterial; the contents of the standard alone must be complied with. That the additional ingredient is plainly set forth on the label is immaterial; the contents of the standard alone must be complied with. As the Court stated in the recent case of *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, where the addition of vitamin D to a product which in other respects complied with the standard for farina was conceded to be a non-conformity to the standard, even though vitamin D was a non-deleterious and even beneficial substance:

"Both the text and the legislative history of the present statute plainly shows that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from 'economic adulteration', by which less expensive ingredients were substituted . . . so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold. Sen. Rep. No. 493, 73d Cong., 2d Sess., p. 10; Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10. The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity 'under which the integrity of food products can be effectively maintained', (H. R. Rep. 2139, 75th Cong., 3rd Sess., p. 2; H. R. Rep. 2755, 74th Cong., 2d Sess., p. 4) and to require informative labeling only where no such standard had been promulgated, . . ."

[*Benzoate of Soda Barred as Ingredient of Tomato Catsup*]

In acting on his own initiative, it was evidently the Administrator's judgment that the promulgation of a standard for tomato catsup would promote honesty and fair dealing in the interest of consumers. After due deliberation being given to benzoate of soda as an ingredient, either in the standard or as a permitted optional, the Administrator's rejection thereof bars the inclusion of that chemical in any food which purports



*U. S. v. 306 Cases "Sandford Tomato Catsup with Preservative"*

to be tomato catsup. It is not necessary to decide this. Court's power to review the Administrator's determination in this respect for, assuming the power, his decision is held to be correct. The evidence indicates that the only purpose in adding benzoate of soda is to effect an economy in the cost of manufacture which amounts to approximately 25% difference in consumer price, resulting in a material economic advantage over competitors who achieve the same preservative quality by the use of a greater quantity of sugar, an approved ingredient. This economic adulteration is the very fraud which the statute was designed to combat. Although the product under seizure is sold only in No. 10 cans (7 lbs.) to institutional users for cocktail sauces and cooking, the evidence indicated that some of it found its way to individuals via unlabeled cruets on the counters of luncheonettes and small restaurants. The Administrator may well have found that honesty and fair dealing required that patrons of these luncheonettes were entitled to assume that the product they were using was the same tomato catsup they would purchase for home consumption. Catsup sold for home use in small bottles did not contain benzoate of soda. This would be a reasonable basis for the Administrator's refusal to amend the standard.

*[Product Not One for Which No  
Standard Promulgated]*

It requires no extensive argument to reveal the obvious fallacy of claimant's contention that its product is one for which no standard has been promulgated. If every food for which a standard has been prescribed would become an entirely different food by the addition of one ingredient which apparently had no effect upon its

taste or appearance, it would be a simple matter to completely evade and circumvent the purpose of food standards.

*[Product Purports To Be Tomato Catsup]*

That the product seized purports to be tomato catsup is apparent from the evidence. The word "purport" is defined in Webster's New International Dictionary (1940) as meaning: "To convey, imply or profess outwardly, as one's (esp. a thing's) meaning, intention, or true character, to have the appearance, often specious appearance, of being, intending, claiming, etc., (that which is implied or inferred)." Certainly the product under seizure gave the appearance of being tomato catsup; it conveyed the impression, implied and professed outwardly, to the ordinary person that it was tomato catsup, and in fact it was just that. Claimant's own witness testified that it looked, smelled and tasted exactly like catsup and that even an expert would have difficulty in differentiating it from tomato catsup without analysis. Some of the invoices called it "tomato catsup" or "catch-up" and made no mention of a preservative. Most of the persons who purchased it thought of it only as catsup and were not aware that it contained benzoate of soda.

*[Product Held Misbranded]*

The evidence clearly shows that the seized product is a food which purports to be tomato catsup, a food for which a definition and standard of identity has been promulgated, and that it does not conform to such standard in that it contains benzoate of soda, an ingredient not approved by the standard. It is therefore misbranded within the meaning of 21 U. S. C. 343 (g) (1) and is herewith condemned.

Settle findings and decree on notice.



**UNITED STATES v. SIX DOZEN BOTTLES, MORE OR LESS, of "Dr. Peter's Kuriko," Labeled in Part: "Alcohol 14 per cent Prepared from the Following Ingredients: Senna, Fennel, Mandrake Root, Peppermint, Spearmint, \* \* \*," Together with Circulars Entitled "Dr. Peter's Kuriko"**

United States District Court for the Eastern District of Wisconsin. Civil Action No. 1495. May 31, 1944. 55 F. Supp. 458.

In the absence of a stipulation between the parties, the power of removal of the court of original jurisdiction, in a seizure action, is limited to directing transfer to a district of reasonable proximity to the claimant's principal place of business, which does not include the district wherein is situated the claimant's principal place of business.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The power of removal is exclusively conferred under the Act upon the court of original jurisdiction, unless there is a stipulation between the parties.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

A claimant is limited to a single application for removal, which must be made to the court of original jurisdiction.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Timothy T. Cronin, U. S. Attorney for the Eastern District of Wisconsin, at Milwaukee, for libelant.

Herrick, Vette & Peregrine, Chicago, Ill.; and Quarles, Spence & Quarles, Milwaukee, Wis., for claimant.

**Opinion on Claimant's Motion to Remove**  
*[Motion for Transfer of Proceeding]*

F. RYAN DUFFY, District Judge: The claimant, an Illinois corporation with its principal place of business at Chicago, moves for an order transferring this proceeding to the United States District Court for the Northern District of Illinois, Eastern Division, asserting that trial in this district would cause it undue hardship, prevent it from making proper proof of its defenses, and cause great inconvenience to its witnesses, even preventing some of them, whose testimony would be material, from attending the trial.

*[Prior Proceeding]*

This proceeding is under the Federal Food, Drug, and Cosmetic Act (52 Stat., Sec. 1040, 21 U. S. C. A., Sec. 301 *et seq.*), and was commenced on December 10, 1943, in the United States District Court for the Western District of Washington, Northern Division. Claimant was allowed to intervene by that court, and on April 18, 1944, on claimant's motion, an order was entered transferring the proceeding to this court "for trial", the district thereof being "a District of reasonable proximity to the intervenor's (claimant's) principal place of business". As claimant had moved the dis-

trict court in Washington that transfer be ordered "to the United States District Court for the Northern District of Illinois, Eastern Division, or to a United States District Court within reasonable proximity of Chicago, Illinois, the principal place of business of said intervenor", its present motion constitutes a second attempt to secure transfer to the district court in Illinois.

*[Statutory Provision Concerning Removal]*

In connection with the right to removals and the exercise thereof, Sec. 334 (a) of the act provides:

" . . . the proceeding pending or instituted shall, on application of the claimant seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial."



*[Power of Removal Limited]*

Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, because the same would not have been and is not authorized. In the absence of stipulation between the parties, the power of removal of the court of original jurisdiction is limited and restricted. Such court is required to order removal to "a district of reasonable proximity to the claimant's principal place of business". Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois.

The power of removal is exclusively conferred under the act upon the court of original jurisdiction, barring of course the existence of a stipulation of the parties on the subject. As the latter element does not obtain in the instant situation, this court has no power to grant the requested removal. In other words, the right to removal is completely exhausted and no longer exists in this proceeding.

*[Statutory Provision Concerning Power of Court to Which Case Was Removed]*

Claimant contends, however, that this court may order the requested removal un-

der Sec. 334 (f) (2) of the Act, which provides:

"The court to which such case was removed shall have the powers and be subject to the duties, for the purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed."

*[Claimant Limited to Single Application for Removal]*

As pointed out, the proceeding was removed, pursuant to the statute, to this court "for trial" and not for any other purpose. The language of the act last quoted is consistent with such limitation and expressly negatives any power in this court to grant further removal on application. A claimant in proceedings of this nature is limited to a single application for removal which must be made to the court of original jurisdiction. My conclusions have complete support in the legislative history of the controlling statutory provisions.

*[Motion for Removal Denied]*

An order denying claimant's motion will be entered.

---

**UNITED STATES v. 74 CASES, MORE OR LESS, EACH CONTAINING  
48 CANS OF A PRODUCT LABELED (CAN)  
"C. C. BRAND OYSTERS"**

United States District Court for the Western District of South Carolina.  
No. 10373. June 29, 1944. 55 F. Supp. 745.

There are no such proceedings in admiralty as motions to remove from one district to another.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

In the absence of express statutory authority, a district court does not have the authority to transfer a case to another district court for trial.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

In the Act, Congress empowered the district courts to remove designated types of seizure actions to other districts for trial. This did not include a libel proceeding charging adulteration, which could not, therefore, be removed.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

O. H. Doyle, for the United States.

A. C. Mann of Greenville, S. C., and White & Morse of Gulfport, Miss., for claimant.

*[Motion To Transfer Libel Proceeding]*

C. C. WYCHE, District Judge: The above libel proceeding is based upon the charge of adulteration of oysters, and is now before me upon the motion of C. C. Company,

intervening claimant, to transfer the cause from this district to the Southern District of Mississippi, where claimant's principal place of business is located.



*[Pertinent Sections of Federal Act]*

Section 304 (a) and (b) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 334 (a) and (b)), sets forth the authority conferred upon district courts to proceed upon or to transfer seizure actions from one district to another.<sup>1</sup>

<sup>1</sup> "(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 344 or 355, be introduced into interstate commerce, *shall be liable to be proceeded against* while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, that no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. *In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.*

"(b) The article shall be liable to seizure by process pursuant to the libel, and procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by

The pertinent portion of section 304 (a) deals exclusively with the removal of libels for condemnation based upon the charge of misbranding. It authorizes removal, with two specified types of exceptions, of a single libel for condemnation where the charge is misbranding.<sup>2</sup>

*jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby."* (Emphasis added) 21 U. S. C. A. 334 (a) (b).

<sup>2</sup> See the final Congressional Conference Report on the Act, House Rep. No. 2716, 75th Cong., 3d Sess., Statement of the Managers on the Part of the House, page 22:

*"Change of venue when only one libel permitted.—Under the House amendment where the number of libels for misbranding is limited to one proceeding, such proceeding shall on application of the claimant seasonably made be removed for trial to a district in a State contiguous to the State of the claimant's principal place of business; such district to be stipulated between the parties, or, if they cannot agree, to be designated by the court to which the application is made. Under the conference agreement the change of venue is to any district agreed upon by the parties, or, if they cannot agree within a reasonable time, the court within which the libel is pending (after reasonable notice and opportunity for hearing to the United States attorney) shall by order, unless good cause to the contrary is shown, provide for the removal of the case to a district of reasonable proximity to the claimant's principal place of business."* (Emphasis added.)



## U. S. v. 74 Cases "C.C. Brand Oysters"

The pertinent portion of section 304 (b) deals exclusively with the consolidation and removal of multiple libels pending in two or more jurisdictions and involving the same claimant and the same issues of adulteration or misbranding.<sup>3</sup>

[No Authority To Transfer Single Libel  
Based on Adulteration]

It will be seen, therefore, that the Act has expressly conferred upon the district courts the authority to consolidate and/or transfer three types of libel proceedings, (1) a single libel based upon a misbranding charge (with some exceptions); (2) multiple libels based upon a misbranding charge; (3) multiple libels based upon an adulteration charge. The Act is silent with respect to the authority of a district court to transfer a single libel based upon an adulteration charge, and such is the nature of the libel involved in this motion.

[Admiralty Procedure Does Not Provide  
for Removal]

Section 304 (b) of the Act requires that the procedure in cases arising under this section "conform, as nearly as may be, to the procedure in admiralty." In *In re Thames Towboat Co.*, 21 F. (2d) 573, (D. C. D. Conn., 1927), a motion was made by one of the parties to remove an admiralty case from the District of Connecticut to the

Eastern District of New York. The Court denied this motion and said, "\* \* \* there are no such proceedings in admiralty as motions \* \* \* to remove from one district to another."

[No Authority to Remove in Absence of  
Express Statutory Authority]

In the absence of express statutory authority a district court does not have the authority to transfer a case to another district court for trial. See, *Billings Utility Co. v. Federal Reserve Bank*, 40 F. Supp. 309 (D. C. D. Montana, 1941); *Spies v. Chicago E. E. I. R. Co.*, 32 Fed. 713, (S. D. N. Y., 1887); *In re Associated Gas & Electric Co.*, 83 F. (2d) 734 (CCA 2, 1936). United States District Courts have no jurisdiction beyond that granted by Congress. *Applegate v. Applegate*, 39 F. Supp. 887.

In the Federal Food, Drug, and Cosmetic Act Congress has empowered the district courts to remove designated types of libel proceedings to other districts for trial. The present libel proceeding is not among those therein designated as removable. I know of no other statute that authorizes its transfer to another district for trial, and none has been called to my attention.

[Motion To Transfer Denied]

For the foregoing reasons, the motion to transfer the above cause is denied.

<sup>3</sup> The final Conference Report on the Act, page 23, is as follows:

"Consolidation of multiple libels.—Under the House amendment when libel proceedings involving the same claimant and the same issues of adulteration or misbranding are pending in two or more district courts, such proceedings upon application of the claimant to one of such courts may be consolidated for trial by order of such court and tried in any district, selected by the claimant, where one of the proceedings is pending, or, if not so selected, in a district contiguous to the State of the claimant's principal place of business, to be agreed upon be-

tween the parties, or, if they cannot agree, to be designated by the court to which the application is made. The conference agreement requires the consolidated to be in a district selected by the claimant where one of the proceedings is pending or in a district agreed upon between the parties, and further provides that if not selected in one of these manners, the court to which the application is made (after reasonable notice and opportunity for hearing to the United States Attorney)—shall by order, unless good cause to the contrary is shown, order the consolidation to be made in a district of reasonable proximity to the claimant's principal place of business." (Emphasis added.)



**UNITED STATES v. 2,640 CASES OF DRIED PRUNES**

United States District Court for the Western District of North Carolina.  
August 14, 1944. Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7277) Issued September 1945.

In a seizure action charging that the food product proceeded against was adulterated, the claimant moved for a transfer of the case to a district of reasonable proximity to its place of business. In denying the motion, the court declared that the removal provisions of Section 304 (a) apply solely to misbranded articles and in no wise cover articles that have been seized by reason of an alleged adulteration.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Section 304 (b) fully covers the removal of certain cases where seizures have been made of allegedly adulterated articles, but the instant proceeding was not among those therein designated as removable.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

*[Right of Removal]*

WEBB, District Judge: It appears to the Court that the movant based his right of removal on Section 334 (a), Title 21, United States Code Annotated; however, the Court is of the opinion that the provisions of said Section applies solely to misbranded articles and in nowise covers articles that have been seized by reason of an alleged adulteration;

It further appearing to the Court that Section 334 (b), Title 21, United States Code Annotated, fully covers the removal from one district to another of certain cases where seizures have been made of alleged adulterated articles, but the above entitled proceeding is not among those therein designated as removable;

*[Motion To Transfer Cause Denied]*

For the foregoing reasons, the motion to transfer and remove the above entitled cause to another district is therefore denied.

[On November 8, 1944, the case having come on for trial before a jury, and a verdict having been returned in favor of the Government, judgment of condemnation was entered and the product was ordered released under bond to be disposed of for purposes other than human consumption, under the supervision of the Food and Drug Administration.]

**UNITED STATES v. 1 DOZEN BOTTLES, MORE OR LESS, EACH  
CONTAINING 400 TABLETS, and 9 2/12 Dozen Bottles, More or  
Less, Each Containing 150 Tablets of an Article Labeled  
in Part "Boncquet Tablets"**

United States Circuit Court of Appeals for the Fourth Circuit. No. 5270.  
Decided December 13, 1944. 146 F. 2d 361.

The court pointed out that the trial court had held that descriptive circulars which were shipped separately from the drug alleged to be misbranded, but which were designed to be used by dealers in connection with the resale of the product, accompanied the product within the meaning of Section 201 (m).

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

There is no necessary conflict between a Federal Trade Commission proceeding, designed to prevent the continuance in the future of unfair and deceptive trade practices, and a seizure action under the Federal Food, Drug, and Cosmetic Act to condemn products which have been unlawfully shipped in the past.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.



*U. S. v. 1 Dozen Bottles "Boncquet Tablets"*

Where the Government instituted a seizure action while a Federal Trade Commission proceeding was pending, the relief sought in the seizure action could not have been granted by the Commission, and consequently the district court was not clothed with a discretionary power to refuse to entertain jurisdiction.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The power of the district court to condemn misbranded articles is not impaired by the power of the Federal Trade Commission to issue a cease and desist order against the shipper in a proceeding pending before it.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

A decision of a court favorable to a manufacturer in a seizure action based on a misbranding charge is a bar to the promulgation of a cease and desist order by the Federal Trade Commission in a proceeding based on the same charge of misrepresentation.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The court pointed out that it has been held that a libel to condemn goods alleged to be misbranded under the Federal Food, Drug, and Cosmetic Act cannot be sustained if the Federal Trade Commission, in a prior proceeding, had found that the statements made by the shipper in respect of the goods were not false or misleading.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

A promise by the claimant of good behavior in the future, and the destruction of offending circulars, do not relieve the offending goods from liability for past actions, and the case is not moot as long as the Government's demand for condemnation remains unheard.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

C. Ross McKenrick, Assistant U. S. Attorney (Tom C. Clark, Assistant Attorney General; Bernard J. Flynn, U. S. Attorney; Joseph L. Maguire, Attorney, Federal Security Agency; and Vincent A. Kleinfeld, Special Assistant to the Attorney General, on brief), for appellant.

Robert H. Carr (Hibbard & Kleindienst on brief), for appellee.

Before PARKER, SOPER and DOBIE, Circuit Judges.

*[Libel Filed for Seizure of Drugs Deemed  
To Be Misbranded]*

SOPER, Circuit Judge: The United States filed a libel for the seizure and condemnation of a quantity of drugs called Boncquet tablets, which had been shipped in interstate commerce from Glenvale, California, to Baltimore, Maryland, on the ground that the goods were misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. A. §§ 301 *et seq.* appendix. The goods were attached and J. Paul Elliott, receiver of Boncquet Laboratories, by appointment of the Superior Court of Los Angeles County, California, filed an answer as claimant and prayed that the libel be dismissed.

*[Descriptive Circulars Shipped Before Drugs]*

When the case came on for hearing, it was shown that the misbranding complained of appeared in certain descriptive circulars which were shipped separately from the goods and designed to be used by dealers in connection with the resale of the goods. In this instance the accused circulars had been shipped before the goods and the shipment of circulars of this kind had been discontinued before the shipment by the manufacturer of the attached goods; but the dealers, to whom the circulars and the goods had been sent, were not notified to withdraw the circulars until after the goods had been received and put on sale in Baltimore. Specifically the distribution of the circulars was discontinued on February 28,



1942. The goods were shipped in April and May, 1942, when the circulars were still in possession of the dealers, and the direction from the shipper to the dealers to destroy the circulars was not issued until August, 1942.

[*Court's Ruling as to Misbranding*]

Upon this set of facts the District Judge, before determining whether or not the circulars misdescribed the goods, ruled preliminarily that the circulars accompanied the goods within the meaning of § 321 (m) of the Act, so as to constitute a misbranding within the meaning of § 331 (b) of the Act, if in fact the circulars falsely described the goods. For decisions bearing on this subject see, *United States v. Research Laboratories*, 9 Cir., 126 F. 2d 42, 45; certiorari denied 317 U. S. 656; *United States v. Lee*, 7 Cir., 131 F. 2d 464, 466; *United States v. 7 Jugs, etc., Dr. Salsbury's Rakos*, D. C. Minn., 53 F. Supp. 746, 755.

[*Hearing Postponed*]

It was then brought to the attention of the court by attorneys for the claimant that a proceeding against the shipper of the goods, based upon similar misdescription of goods shipped in interstate commerce, had been instituted before the Federal Trade Commission prior to the filing of the libel in this case and was still pending. The court thereupon postponed the hearing of the libel so that it might be definitely ascertained whether the Federal Trade Commission intended to proceed with the case before it or to abandon it, with leave to the United States in the latter event or in the event that the same issues were not involved in the two proceedings, to move to put the libel case back on the trial docket of the District Court.

[*Holdings of Court Listed*]

Subsequently, the receiver and claimant of the goods filed a motion in the instant case supported by affidavit to dismiss the libel on the two grounds that the same issues were still pending before the Federal Trade Commission and that the instant case had become moot because after the libel was filed, the formula of the goods had been revised and the distribution of the circulars complained of had been discontinued. The court granted this motion and dismissed the case for the reasons and upon the findings of fact set out in an accompanying opinion. Therein the court

held (1) that the issues in the libel case had become moot in that the label on the bottles and the accompanying circulars had been changed by the claimant and none of the drug so labeled or the accused circulars had been distributed for more than two years; (2) that the claimant had given assurances that there would be no further shipment of goods accompanied by the labels or circulars objected to; (3) that the claimant had obtained the approval of the California court for the use of a new label and the manufacture of the goods under a changed formula, and had been ordered by that court to cease and desist from the distribution of the prior labels and circulars; (4) that all dealers had been directed to destroy the accused circulars and pamphlets, and (5) that for all practical purposes the same issues were involved in the pending action before the Federal Trade Commission so that to proceed with the libel case under the circumstances appeared to be duplicitous, costly and unnecessary.

[*Power of Court To Condemn Misbranded Drugs Not Affected by Power of Federal Trade Commission To Issue Cease and Desist Order*]

No copy of the complaint or of the answer or of the testimony taken in the proceeding before the Federal Trade Commission was introduced in evidence in the pending case, and the court's conclusion was based upon the general statement of counsel for the opposing parties that essentially the same issues were involved in both cases. In the absence of more definite proof, we shall assume that the jurisdiction of the Commission was invoked under the Federal Trade Commission statute, 15 U. S. C. A. §§ 45, 52 and 53, to enjoin the shipper of the drugs from using unfair or deceptive acts or practices and from disseminating false advertisements to induce the purchase of the drugs in interstate commerce. Obviously there is no necessary conflict between such a proceeding, which is designed to prevent the continuance in the future of unfair and deceptive trade practices, and a libel under the Federal Food, Drug, and Cosmetic Act which invokes the power of the court to seize and condemn falsely branded goods which have been unlawfully shipped in interstate commerce in the past. The relief sought in the libel suit, that is, the condemnation of the offending shipment, could not have been granted by the Federal Trade Commission, and consequently it



*U. S. v. 1 Dozen Bottles "Bonquet Tablets"*

cannot be said that the court was clothed with that discretionary power to refuse to entertain jurisdiction which a court has when a prior action between the same parties involving the same issue has been filed in another court which has the power to adjudicate all the rights of the parties. There was no occasion for the application of the principle that the pendency of a prior action or suit, predicated on the same cause of action between the same parties, constitutes good ground for the abatement of a later action or suit. See *Maryland Casualty Co. v. Boyle Construction Co., Inc.*, 4 Cir., 123 F. 2d 558, 564. It has been correctly held that the power of the District Court to condemn misbranded articles is not impaired or affected by the power of the Federal Trade Commission to issue a cease and desist order against the shipper in a proceeding pending before it. *United States v. Research Laboratories, Inc.*, 9 Cir., 126 F. 2d 42, 45; *Sekov Corp. v. United States*, 5 Cir., 139 F. 2d 197.

[Indefinite Showing of Precise Status of Proceeding]

It is true that a decision of a court favorable to the manufacturer in a libel proceeding brought by the United States for the condemnation of goods alleged to have been misbranded is a bar to the promulgation of a cease and desist order by the Federal Trade Commission in a proceeding based on the same charge of misrepresentation of the character of goods shipped in interstate commerce; *George H. Lee Co. v. Federal Trade Commission*, 8 Cir., 113 F. 2d 583; and conversely it has been held that a libel to condemn goods alleged to have been misbranded under the Federal Food, Drug, and Cosmetic Act cannot be sustained if the Federal Trade Commission in a prior proceeding has found that the statements made by the shipper in respect to the goods were not false or misleading. *United States v. Willard Tablet Co.*, 7 Cir., 141 F. 2d 141. But there has been no determination by the Federal Trade Commission of the issues raised in the pending case. Indeed there is no definite showing of the precise status of the proceeding before the Commission. All we know is that a complaint was filed on December 8, 1938, some testimony was taken in California in September, 1942, and

some effort has been subsequently made by the judge of the California court and by the claimant-receiver to induce the Federal Trade Commission not to issue a cease and desist order because the formula of the goods and the advertising matter relating thereto have been changed, and the shipper has directed the dealers to destroy all the old circulars on hand. What course the Federal Trade Commission will pursue in the future no one undertakes to say. For all that we know, the proceeding before that body may be abandoned or dismissed without further action. It seems clear that the claimant seeks the dismissal of the pending libel suit on the ground that the proceeding before the Federal Trade Commission involves the same issues and at the same time is seeking the dismissal of the latter proceeding on the ground that prior practices alleged to have been deceptive have been abandoned.

[Trial Court Should Hear and Determine Charges of Libel Upon the Merits]

What has been said is a sufficient answer to the suggestion that the pending case is moot because the offending circulars have been withdrawn and destroyed and the claimant has given the court assurance of good behavior in the future. Such a promise does not relieve the goods from liability for past actions and the case is not moot so long as the demand of the United States for condemnation of the goods remains unheard. Under the circumstances, we think that the trial court was not clothed with discretion or authority to decline jurisdiction. It should proceed to hear and determine the charges contained in the libel upon the merits since the right of a party litigant to the judgment of a court upon a matter properly before it is a fundamental aim of the law. *Cohen v. Virginia*, 6 Wheaton 264, 404; *Wilcox v. Consolidated Gas Co.*, 212 U. S. 19, 40; *McClellan v. Garland*, 217 U. S. 268, 282; 35 Am. Jur. (Mandamus) § 254, p. 25.

[Judgment Reversed and Remanded]

The judgment of the District Court is reversed and the case remanded for further proceedings.

*Reversed.*



UNITED STATES v. 75 CASES, MORE OR LESS, EACH CONTAINING  
24 JARS OF PEANUT BUTTER, LABELED IN PART (JARS):  
"TOP NOTCH BRAND" AND CONSOLIDATED CAUSES

United States Circuit Court of Appeals for the Fourth Circuit. No. 5254.  
Decided December 27, 1944. 146 F. 2d 124.  
Certiorari denied, 325 U. S. 856 (1945).  
Reversing 54 F. Supp. 641. See page 82.

Section 703 of the Act was enacted to provide a compulsory method by which information of interstate shipments may be obtained from carriers.

Section 703, Federal Food, Drug, and Cosmetic Act.

Section 703 does not require that investigation must be limited to the records of the classes of persons therein enumerated. The prescribing of certain compulsory methods of investigation does not exclude investigation made pursuant to permission given.

Section 703, Federal Food, Drug, and Cosmetic Act.

Section 703 affords to the Government a cumulative procedure for obtaining information without restricting other avenues of information.

Section 703, Federal Food, Drug, and Cosmetic Act.

In a seizure action, where the manufacturer's invoices were examined by a Government inspector to ascertain where shipments were being made, it was held that permission to inspect the invoices had been given voluntarily and that the Government was free to use the information in the seizure proceedings.

Section 703, Federal Food, Drug, and Cosmetic Act.

A seizure action is not a criminal proceeding within the Fourth Amendment to the Constitution. Libels for condemnation are proceedings *in rem*, and no violation of the "Search and Seizure" Clause of the Amendment was created by utilizing, in a seizure action, information obtained from an inspection of the manufacturer's invoices.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Under the Act, adulterated goods are subject to seizure and destruction irrespective of the intent of the manufacturer.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

It is not improper for a Government inspector to combine a factory inspection and an examination of the claimant's invoices.

Sections 703, 704, Federal Food, Drug, and Cosmetic Act.

The taking of samples by a Government inspector is authorized under Section 702 (b) of the Act.

Section 702 (b), Federal Food, Drug, and Cosmetic Act.

C. Ross McKenrick, Assistant U. S. Attorney (Bernard J. Flynn, U. S. Attorney; Vincent A. Kleinfeld, Special Assistant to the Attorney General, and Alvin M. Loverud, Attorney, Federal Security Agency, on brief), for appellant.

Raymond M. Hudson and J. Charles Fagan, for appellees.

Before PARKER, SOPER and DOBIE, Circuit Judges.



*U. S. v. 75 Cases of Peanut Butter "Top Notch Brand" etc.**[Appeal from Judgment Impounding Government Evidence and Dismissing Libels]*

DOBIE, Circuit Judge: This is an appeal from an order and judgment of the District Court impounding certain evidence and documents, and dismissing five libels for condemnation, consolidated for trial, brought pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. A. § 301 *et seq.* (hereinafter called the Act). The evidence and documents were impounded, and the Government prohibited from using them and any information obtained therefrom, on the assumption that the evidence, documents and information were obtained by a government representative wrongfully and in violation of certain provisions of the Act. The opinion of the District Court is reported in 54 F. Supp. 641.

*[Facts of Case]*

The Old Dominion Peanut Corporation (hereinafter referred to as claimant) is a corporation with its place of business in Norfolk, Virginia, engaged in manufacturing peanut butter and peanut candies. On or about October 15, 1943, one Rankin, an inspector for the Food and Drug Administration, went to claimant's plant for the purpose of making an inspection of the factory, under authority of Section 374 of the Act. He saw Stubbs, claimant's president, and revealed the purpose of his visit. Stubbs made no objection. An inspection of the factory was made and Rankin found rodent pellets and refuse in and around the food products. Chapman, claimant's plant superintendent, secured containers for Rankin and samples of the food products were taken.

After the completion of the factory inspection, Rankin asked to see the company invoices for the purpose of ascertaining where shipments of these food products were being made. Mizzell, the claimant's sales manager, produced the invoices for Rankin's inspection. No objection whatever was made by either Stubbs or Mizzell.

Subsequently, on November 1, 1943, Rankin returned to claimant's plant for another inspection. Stubbs gave Rankin permission to make the inspection and take photographs of unsanitary conditions. The inspection again showed the presence of rodent pellets and refuse. Rankin photographed and took as evidence a dead mouse found in the candy manufacturing room. Rankin testified that he informed Worsham, claim-

ant's secretary-treasurer, of the unsanitary conditions and advised him that legal proceedings might result. Rankin again asked for permission to inspect claimant's invoices and this permission was once more granted, without objection. He made notations of claimant's interstate shipments. Later certain shipments of these food products were seized and, on analysis showing the presence of filth in the food products, the instant libels for condemnation were brought.

*[Findings of District Court]*

The District Court found, and we agree with this finding, that permission to inspect the factory was fully and freely given. Further findings were made to the effect that permission was given to Rankin to inspect the claimant's invoices; but the District Court held that this permission was secured by a method that "smacks of surprise, if not of actual misrepresentation." This finding was predicated on the Court's interpretation of the requirements of Section 373 of the Act, and was, we think, clearly erroneous. F. R. C. P., Rule 52 (a), 28 U. S. C. A. following § 723c.

*[Statutory Provision Involved]*

Section 373 of the Act provides as follows:

"For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates."

*[Position Taken by Court Below]*

The Court below has taken the position, that since Section 373 "meticulously" sets out the method by which information as to interstate shipments is to be obtained, should the Government choose to avail itself of any other method, it must make a full and complete disclosure to the claimant



and make sure that claimant's consent is not due in any respect to a failure to understand the fullest use to which the records might be put by the Government.

[*Narrow Construction Not Warranted*]

While we agree that in no case should the Government be permitted to use fraudulent methods in obtaining evidence, we think that the District Court has here placed an unduly narrow construction on this statute. No such interpretation is warranted, either by the words of the Act, by its purpose, or by its legislative history.

[*Statute Does Not Limit Investigation of Records*]

Section 373 was enacted to provide a compulsory method by which information of interstate shipments, necessary to the enforcement of the Act, might be obtained from carriers. The need for such a method is obvious since interstate transportation is, in large part, done by common carriers. The lack of such a provision had proved a definite handicap to the enforcement of the Act. H. R. Report No. 2139—75th Cong. 3rd Session. But this section does not require that investigation must be limited to the records of the classes of persons therein enumerated. Nothing in the legislative history of the Act indicates any such intent on the part of Congress.

[*Prescribing of Compulsory Investigation Does Not Exclude Permissive Investigation*]

Claimant contends here, as it did below, that since the Act provides that the records of carriers and receivers may be examined, this excludes the examination of the claimant's records. We agree with the District Court that the prescribing of certain compulsory methods of investigation does not exclude permissive investigation. The affidavit filed by Stubbs clearly shows the unfortunate result which would follow from a contrary view. The affiant there states that one of the interstate shipments involved was moved by the purchaser in his own truck. Such an instance reveals the difficulties confronted by those administering the Act, should permissive examination of the shipper's records be denied. In such cases there would be no common carrier's records to be examined. Such a view would clearly not be in conformity with the purposes of the Act.

[*Claimant Not Really Misled*]

We need not consider the question of claimant's rights had it refused to allow Rankin's inspection of its invoices. The District Court found that such permission was given. We think that claimant has no grounds for contending, nor the District Court for finding, that claimant was really misled. Claimant's officers well knew, or must have known, that, should the plant inspection justify the sampling of products shipped in interstate commerce, this would be done. Further, Stubbs admitted that he was "generally" familiar with the Act, and in the light of his experience he must have been aware, at least such knowledge is legally imputable to him, that should the sampling disclose filth, the products would certainly be subject to condemnation. This is the obvious and only practical inference to be drawn from these facts.

[*Government Free To Use Information Gleaned*]

In connection with Section 373 of the Act, there is no ground for the application of the maxim *expressio unius est exclusio alterius*. We interpret this section, rather as affording a cumulative procedure to the Government, without restricting other avenues of information. Nor are we impressed by the statement of claimant's president (who, without any remonstrance or protest, gave Rankin free access to the invoices) that he would not have granted this access if he had not thought Rankin had a legal right to such access or if he had known that the information thereby gleaned might be used in subsequent libel proceedings. Permission to inspect the invoices was still voluntary and the Government was free to use this information in the proceedings for libel. See *Joong Sui Noon v. United States*, 76 F. (2d) 249, 251.

[*No Violation of "Search and Seizure" Clause*]

We are not here dealing with a criminal proceeding within the 4th Amendment to the Constitution. *United States v. 935 Cases, etc.*, 136 F. (2d) 523 (C. C. A. 6, 1943), cert. denied, 320 U. S. 778. These libels for condemnation are proceedings *in rem*, and we agree with the Court below that there has been no violation of the "search and seizure" clause of the 4th Amendment. *United States v. 935 Cases, etc., supra*. Public interest demands such a construction as will further the purposes of the Act. *United States v. Research Laboratories*, 126 F. (2d) 42, cert. denied, 63 S. Ct. 54.



[*Boyd Case Distinguished*]

Claimant relies on *Boyd v. United States*, 116 U. S. 616, in support of its contentions. Several factors impel the view that the *Boyd case* has no application here. That case involved an unconstitutional demand for the production of records in a criminal proceeding. If the records were not produced (in the *Boyd case*) the allegations were to stand as admitted. No such question arises here. By a specific proviso in Section 373 of the Act such information received may not be used in a criminal prosecution of the person giving the information. Nor was the plate glass involved in the *Boyd case* an outlaw of interstate commerce. It was subject to forfeit only because of the illegal acts of its owner. Under the Act, condemned goods are subject to seizure and destruction irrespective of the intent of the manufacturer. *United States v. Buffalo Pharmacal Co.*, 131 F. (2d) 50 (C. C. A. 2, 1942).

[*Proper To Combine Factory Inspection and Examination of Invoices*]

Claimant further contends that it was improper for the inspector to combine a factory inspection and an examination of the claimant's invoices. It can hardly be assumed that the activities of the Food and Drug Administration are of a pigeon-hole nature which demand canalized separation. The Administration operates as a unit in furtherance of its primary purpose—the protection of the public. It is not unreasonable to assume that packaged food in which filth is found will be sold by the producer.

Further, not only is it commensurate with the purpose of the Act to ascertain the interstate destination of the food in order to sample it for filth, should the factory inspection justify such action; but any other procedure would tend to frustrate the entire purpose of the Act. There was nothing wrongful in either the method of obtaining the information, or in the use of the information voluntarily granted. *Joong Sui Noon v. United States*, *supra*.

There is no legal merit in the contention that the Administration must use other and more expensive and time consuming methods of investigation instead of using information voluntarily given. Nor do we find approval for claimant's position that had Rankin not received the information from its invoices, there would have been no means of tracing the adulterated food shipped in the purchaser's truck. The Administration is not indulging in a game of "hide and seek." Its efforts are expended in the protection of the public.

[*Taking of Samples Legal*]

Finally, claimant contends that the taking of samples by Rankin was illegal. This, we think, is also without merit. Section 372 (b) of the Act clearly contemplates the taking of samples.

[*Judgment Reversed and Cause Remanded*]

The judgment of the District Court is reversed and the cause is remanded to that Court for further proceedings consistent with this opinion.

*Reversed and Remanded.*

---

**C. C. COMPANY v. UNITED STATES**

United States Circuit Court of Appeals for the Fifth Circuit. No. 10962.  
October 30, 1944. On Rehearing, January 20, 1945. 147 F. 2d 820.

Though condemnation proceedings conform, as nearly as may be, to the procedure in admiralty, Rule 81 (a) (2) of the Federal Rules of Civil Procedure provides that the rules govern appeals in proceedings for forfeiture of property for a violation of a Federal statute.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The findings of fact of a trial court in a seizure action must be accepted as true unless they are clearly erroneous, pursuant to Rule 52 (a), Federal Rules of Civil Procedure.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Statutes enacted for the public good, although they impose penalties or forfeitures, are not to be construed strictly in favor of the defendant but should be reasonably construed so as to carry out the intention of Congress.

Title, Federal Food, Drug, and Cosmetic Act.



The Federal Food, Drug, and Cosmetic Act was enacted in the interests of the public welfare, and courts must give it effect according to its terms.

Title, Federal Food, Drug, and Cosmetic Act.

In a seizure action against oysters charging adulteration, it was held, on petition for rehearing, that there was substantial evidence to warrant the finding of the trial court that the oysters were in part decomposed, and that the decree of condemnation must therefore be affirmed.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

S. E. Morse of Gulfport, Miss., for appellant.

T. Hoyt Davis, U. S. Attorney, and John P. Cowart, Assistant U. S. Attorney, both of Macon, Ga., Vincent A. Kleinfeld, of counsel, for the United States.

Before HOLMES, WALLER, and LEE, Circuit Judges.

[*Whether Condemned Oysters Were Adulterated*]

LEE, Circuit Judge: The appellee by separate proceedings *in rem* sought to condemn two interstate shipments of canned oysters packed by appellant at its plant in Biloxi, Mississippi. One shipment of 179 cases, each containing 48 cans of "C. C. Brand Oysters," was consigned to Webb-Crawford Company, Athens, Georgia, and the other shipment of 49 cases, each containing 48 cans of "C. C. Brand Oysters," was consigned to Thornton Grocery Company, Elberton, Georgia. The actions, brought under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A., Section 301, *et seq.*, were consolidated for trial and tried to the court without a jury. The court found that one lot of oysters, code number 4J70, was not adulterated, was fit for food, and ordered it released. The remaining lots were found adulterated, unfit for food, and were ordered destroyed. The sole issue is whether the oysters were adulterated in violation of 21 U. S. C. 342 (a) (3) in that they were wholly or partially decomposed.

[*Admiralty Procedure*]

The Federal Food, Drug, and Cosmetic Act, after providing for condemnation proceedings by libel, with reference to procedure, provides:

"The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury . . ." 21 U. S. C. Section 334 (b).

The rule in this court in admiralty cases is that the hearing on appeal is *de novo*, and that it is the appellate court's duty to review the whole case and make such decree

as ought to have been made. *Pavlis, et al. v. Jackson*, 131 F. (2d) 362; *Coryell v. Phipps*, 128 F. (2d) 702, 704.

[*More Than Preponderance of Evidence Required for Forfeiture*]

Where forfeiture of private property is sought, as is here sought by the Government, "a higher degree of proof than a mere preponderance, a mere balance of evidence in favor of the Government is required. It is necessary in a case like this, that the Government should establish, by clear and satisfactory evidence, that its cause has been made out." *Van Camp Sea Food Company v. United States*, 82 F. (2d) 365.

[*Evidence*]

To prove its case, the Government offered the testimony of two officers: Dr. Albert C. Hunter, Chief of the Bacteriological Division of the Food, Drug, and Cosmetic Administration; and Raymond L. Vandever, Chief Chemist in charge of the New Orleans office of the same Administration. Both witnesses examined the oysters organoleptically, that is, smelled them. Each can was carefully opened, the liquid drained off into a pan, and "then the oysters were very carefully smelled and examined." Both agreed that in appearance the oysters were perfectly normal.

Dr. Hunter examined a total of 168 sample cans from the Webb-Crawford Company shipment and found 12 cans, or 7%, definitely rotten and 4 cans, or about 2%, with some degree of decomposition; the remaining cans he classed as passable. He examined 48 sample cans from the Thornton Grocery Company shipment and found one can definitely decomposed. The "off" oysters were from code numbers 4J80 and 4J90. Oysters from code number 4J70 were normal in appearance and smell.



Mr. Vandever examined 24 sample cans of oysters from the Webb-Crawford shipment and 48 cans from the Thornton Grocery Company shipment. Both sample lots contained cans from each code number. Of the 24 samples examined, he pronounced about 24% bad; and of the 48 samples examined, he pronounced 14% rotten, 4% slightly decomposed.

The evidence makes clear, however, that oysters from sandy bottoms, from mud bottoms, and from reefs near the mouth of the Mississippi River are packed in appellant's plant at Biloxi, Mississippi; and that the odor of an oyster or of any other sea food depends on the area from which it is caught. An oyster from a sandy bottom has an odor different from that of an oyster from a mud bottom, and an oyster from near the mouth of the Mississippi River has an odor reflecting contact with sulphur, not found in oysters from sandy or mud bottoms. This characteristic of oysters was testified to by every witness introduced by either party who gave evidence respecting the fitness of the oysters here involved for food.

Dr. Hunter also admitted that whether the odor of an oyster reflected good or bad condition was a matter of personal judgment. Mr. Vandever, who testified that he trained his sense of smell by using experimental packs of oysters "packaged at different stages of decomposition," admitted that men who daily handle sea foods for a livelihood develop through their work a high sense of smell.

Following the seizure of the oysters, appellant obtained 164 sample cans and had them examined by the research department of the American Can Company Southern, in New Orleans. The Government offered in evidence a copy of the report of that examination, in which it was stated that the appearance of the oysters was comparable to that of oysters in normal cans, but that of the 60 cans coded 4J80 and of the 19 cans coded 4J90, "eleven cans in each lot had an abnormal odor comparable to that associated with oysters which have undergone partial decomposition before canning." Upon the suggestion of the trial judge, the depositions of Mr. Lamberton and Mr. Riester, employees of the American Can Company who had made the test, were taken. In explanation of the language in the report, Mr. Lamberton said:

"I believe that the statement there intended not to show that the oysters were

decomposed, but, as stated, there was an odor there which we have associated with oyster decomposition. The particular oysters in those samples themselves, we were remarking only about the odor of the oysters."

Lamberton and Riester in making their test opened the cans, smelled the liquid, poured off the liquid, placed the oysters on a rack and smelled them, then crushed the oysters in the hands and smelled them. Only when the oysters were crushed in the hands was there an "off" odor. They testified as follows:

"Q. In checking code 4J70 in regard to appearance and odor, the cans were normal in every respect?

A. Yes, sir.

Q. Both from a standpoint of odor and after crushing?

A. Yes, sir.

\* \* \* \*

Q. What was the only time with reference to code 4J80 that any abnormal or off odor was noticed, Mr. Riester?

A. When the oysters were picked up in the hand and crushed and smelled *with the nose close to the oyster.*

\* \* \* \*

Q. With reference to Code 4J90, were you able to detect abnormal or off odor when these cans were opened?

A. Only by crushing."

Neither Lamberton nor Riester could say what caused the odor in the oysters they crushed.

Mr. Lamberton said:

"Q. You still could not state, Mr. Lamberton, whether the odor that you got came from the ground where the oysters were feeding, which was on the mud flats in the sulphur bottom, or whether it came from decomposition?

A. I could not state that. I defined the odor as similar to decomposition, but could not say definitely that I know it was decomposition or anything else."

Mr. Riester said:

"Q. In these cases where you have not been able to detect the odor until after you have crushed an oyster and crushed its intestines and its body, it is possible, is it not, for any off odor or abnormal odor to come from whatever food the oyster has eaten while on the bottom of the water?

A. That is correct."

Appellant's witnesses were all identified with the oyster-packing business in and around Biloxi, with years of experience in that business. Elmer Williams was with the DeJean Packing Company, one of the



largest independent plants in the United States, and had been in its employ twenty-two to twenty-three years. Nick Mavar was with the Mavar Shrimp & Oyster Company, another large company. C. A. Delacruz was mayor of Biloxi and manager of the Southern Shell Fish Company, owned by the Wesson Oil Company, and had been in the sea food business some thirty-five years. William Cruso was president of the C. C. Company, appellant, and had been in the oyster-packing business since the close of the first World War. All of them told of odors given off by oysters caught on sandy bottoms, on mud bottoms, and from near the mouth of the Mississippi River where sulphur was present. All of them stated that an oyster from a sandy bottom had a normal odor; from a mud bottom, a slightly decomposed odor; and from near the mouth of the Mississippi River, a sulphur odor. They stated that the method of packing oysters and the equipment used by appellant were sanitary and standard. According to the testimony of these witnesses, each boat-load of oysters packed at the packing plants were coded separately; sometimes the boat-load came from one bed, oft-times from several different beds; the boats went out and returned on schedule and were manned by experienced crews who, receiving no pay for bad oysters, consequently watched the catch and brought them in before deterioration; and the oysters were inspected as they were unloaded and inspected again as they passed through the plant. All the witnesses were positive that few if any bad oysters were ever packed in cans.

At the request of appellant, a cross section of the canned oysters was tested during the trial. One can from code 70, four cans from code 80, and twenty-four cans from code 90, were examined organoleptically by all of the witnesses who testified in court. Dr. Hunter pronounced five of the twenty-four cans from code 90 as decomposed; Mr. Vandever found one can of four cans from code 80 decomposed, and six cans of the twenty-four cans from code 90 decomposed or partially so. Appellant's witnesses, all experienced oyster packers, were unanimous and positive in pronouncing the oysters good canned oysters, including those in the cans referred to by Dr. Hunter and Mr. Vandever as decomposed or partially so. Mr. Mavar offered to eat the oysters said to be decomposed, and Mr. Cruso did eat two of them.

*[Government Failed To Meet Burden of Proof]*

Where a food product is tested for imperfections by the sense of smell, the testimony of men who have had years of experience in handling and processing such product is entitled to at least as much weight as that of Government experts trained by use of "experimental packs" to differentiate between the good and the bad. No test other than that of smell was made by the Government experts, nor did they offer any explanation why other tests were not made. Upon consideration of the whole testimony, we think that the Government has failed to meet the burden resting upon it.

*[Libel To Be Dismissed]*

The judgment appealed from is reversed, and the cause is remanded with directions to dismiss the libel.

**On Rehearing**

*[Burden of Proof on Government; Admiralty Procedure]*

LEE, Circuit Judge: When this case was submitted to this court on appeal it was asserted in the briefs for both parties that, since the action was to compel a forfeiture, the burden was upon the Government to prove by clear and convincing evidence that the oysters shipped in commerce as food were decomposed in whole or in part. Counsel on the argument stated that this court heard the case in the manner of admiralty appeals by reason of the statutory provision that, in condemnation proceedings under the Federal Food, Drug, and Cosmetic Act, the procedure should conform as nearly as may be to the procedure in admiralty.

*[Evidence of Decomposition Not Clear and Convincing]*

Acting under these assurances, this court reviewed the evidence in the light of these principles and reached the conclusion that, while there was evidence of a substantial character indicating that the oysters were partially decomposed, the proof on this material issue was not clear and convincing. In our opinion rendered October 30, 1944, 145 F. (2) 462, the judgment accordingly was reversed and the cause remanded with direction that the libel be dismissed.

*[Government Contention on Petition for Rehearing]*

Upon petition for rehearing the Government with apologies retracted its former representations relative to the burden of



proof, taking the position that it was only obliged to prove its case by a preponderance of the evidence in the trial court, and that the scope of review on appeal was limited, as in other civil cases, by Rule 52 of the Federal Rules of Civil Procedure requiring that the findings of fact of the trial court be not set aside unless clearly erroneous. These matters being vital to a determination of the appeal, we granted a rehearing.

[*Trial Court's Findings Accepted as True  
Unless Clearly Erroneous*]

Though such condemnation proceedings conform, as nearly as may be, to the procedure in admiralty in the trial court, it is expressly provided by Rule 81 (a) (2) of the Federal Rules of Civil Procedure that said rules govern appeals in proceedings for forfeiture of property for violation of a statute of the United States. Cf. *443 Cases of Egg Product v. United States*, 226 U. S. 172. Therefore the case on appeal is not heard anew, but the findings of fact of the trial court must be accepted as true unless they are clearly erroneous. Rule 52 (a), Federal Rules of Civil Procedure.

[*Food, Drug, and Cosmetic Act To Be  
Reasonably Construed*]

It is the general rule that statutes impos-

ing forfeitures, being penal in nature, are to be strictly construed in favor of the defendant.<sup>1</sup> The requirement in condemnation cases of a higher degree of proof than a mere preponderance is a natural corollary of this rule of construction.<sup>2</sup> But in *United States v. Stowell*, 133 U. S. 1, it was held that statutes enacted for the public good and to suppress a public wrong, although they impose penalties or forfeitures, are not to be construed strictly in favor of the defendant but should be fairly and reasonably construed so as to carry out the intention of Congress.<sup>3</sup> The Federal Food, Drug, and Cosmetic Act was enacted in the interests of the public welfare to protect the public health, and courts must give it effect according to its terms.<sup>4</sup>

[*Condemnation Affirmed as Supported by  
Substantial Evidence*]

In our prior opinion we set forth the evidence in detail. It is readily apparent from that discussion that there was substantial evidence to warrant the finding of the trial court that the oysters were in part decomposed. The decree of condemnation entered thereon was therefore correct.<sup>5</sup> The judgment heretofore entered herein is set aside, and the judgment appealed from is affirmed.

<sup>1</sup> *Farmers' & M. National Bank v. Dearing*, 91 U. S. 29; *United States v. One Ford Coach*, 307 U. S. 219; *United States v. Lacher*, 134 U. S. 624.

<sup>2</sup> *Van Camp Sea Food Company v. United States*, 82 F. (2) 365.

<sup>3</sup> See also *Taylor v. United States*, 3 How. 197; *United States v. State Bank*, 6 Pet. 29; *Beaston v. Farmers' Bank*, 12 Pet. 102.

<sup>4</sup> *United States v. Antikamnia Company*, 231 U. S. 654; *United States v. Lexington Mill Company*, 232 U. S. 399, 409; *United States v. Dotterweich*, 320 U. S. 277; *A. O. Andersen & Company v. United States*, 284 F. 542; *United States v. 48 Dozen Packages of Gauze*, 94 F. (2) 641; *United States v. Research Laboratories*, 126 F. (2) 42.

<sup>5</sup> 21 U. S. C. A. Secs .342 (a) (3) and 334 (a).



UNITED STATES v. 1851 CARTONS, MORE OR LESS, each  
 containing 15 pounds of frozen whiting labeled in part  
 "H. & C. Famous Booth Sea Foods Whiting  
 Frosted Fish," and Booth Fisheries  
 Corporation, claimant-appellee

United States Circuit Court of Appeals for the Tenth Circuit. No. 2960.  
 January 8, 1945. 146 F. 2d 760.  
 Reversing 55 F. Supp. 343. See page 110.

One of the declared purposes of the Act is to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics.

Title, Federal Food, Drug, and Cosmetic Act.

The trial court had held, in a seizure suit charging adulteration under Section 402 (a) (3), that, although the fish seized consisted in part of a decomposed substance, it was nevertheless fit for human consumption and was therefore not adulterated. This was erroneous. The courts have uniformly held that when a food consists in whole or in part of a decomposed substance its interstate shipment is prohibited, whether otherwise considered fit for human consumption or not.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The added clause in Section 402 (a) (3) "or if it is otherwise unfit for food" is in the disjunctive and does not condition, qualify, or obscure the plain meaning of the whole sentence when considered in its context.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Bart W. O'Hara (Thos. J. Morrissey, U. S. District Attorney was with him on the brief), Vincent A. Kleinfeld, and James B. Goding, of counsel, for appellant.

Hyman D. Landy (Graham Susman was with him on the brief), for appellee.  
 Before PHILLIPS and MURRAH, Circuit Judges, and RICE, District Judge.

*[Government Appeals from  
 Dismissal of Libel]*

MURRAH, Circuit Judge: In pursuance of Section 304 (a) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (52 Stat. 1040, 21 U. S. C. A. 301 *et seq.*) the United States instituted a libel of information in the United States District Court for the District of Colorado, seeking condemnation of approximately 1851 cartons of frozen fish, each containing 15 pounds, and allegedly consisting "wholly or in part of a decomposed substance", which had been shipped in interstate commerce from the state of Massachusetts into the state of Colorado. The Booth Fisheries Corporation, as claimant, answered admitting the shipment in interstate commerce, but denying the allegation with respect to adulteration. Upon facts which are conclusive here the trial court found that approximately 6% of the entire shipment consisted of decomposed substance, but dismissed the libel on the grounds that it was not "sufficiently decomposed" to be unfit for human consump-

tion, and therefore was not "adulterated" within the meaning and purposes of the Act. The Government has appealed.

*[Purpose of Act and Remedies Provided]*

One of the declared purposes of the Federal Food, Drug, and Cosmetic Act is to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics. *U. S. v. Dotterweich*, 320 U. S. 277, 280; *McDermott v. Wisconsin*, 228 U. S. 115, 128; *Hipolite Egg Co. v. United States*, 220 U. S. 45, 54. To effectuate that purpose the Act prescribes injunctive remedies (Sec. 302 (a) (b)) and criminal penalties (Sec. 303 (a) (b) (c)) for violations, and in addition thereto (subject to enumerated exceptions and limitations) specifically authorizes the seizure and condemnation of any "adulterated" food which is introduced or received in interstate commerce by a libel proceeding in any district court within the jurisdiction of which the adulterated food is found. Sec. 304 (a).



[Question as to Adulteration]

Section 402 of the Act pertinently provides that a food shall be deemed to be adulterated "if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food", and the sole question presented by this appeal is whether frozen fish in 15 pound cartons found to consist of approximately 6% decomposed substance is adulterated and therefore subject to condemnation under the Act.

[Trial Court's Holding]

The trial court held in substance that although the product seized consisted wholly or in part of a decomposed substance it was nevertheless fit for human consumption and was therefore not adulterated within the meaning of the statutory definition and the same argument is made here in support of the trial court's judgment.

[Food Adulterated if in Part Decomposed]

We cannot agree with the trial court's interpretation of the statutory definition of "adulterated" food. Before the amendment of June 25, 1938, sub-section 6 of section 7 of the original Act of June 30, 1906 (34 Stat. 768) provided that an article should be deemed to be adulterated "if it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food \* \* \*". Giving effect to the objects and purposes of the legislation, the courts have uniformly held that when a food consisted "in whole or in part of filthy, decomposed, or putrid animal or vegetable substance" its interstate shipment was prohibited whether otherwise considered as fit for human con-

sumption or not. *United States v. Two Hundred Cases of Adulterated Tomato Catsup*, 211 F. 780, 782; *Anderson & Co. v. United States*, 284 F. 542; *United States v. Krumm*, 269 F. 848; *United States v. Two Hundred Cases of Canned Salmon*, 289 F. 157; *Knapp v. Calaway*, 52 F. 2d 476; *United States v. One Hundred Thirty Three Cases of Tomato Paste*, 22 F. Supp. 515.

Notwithstanding this strict construction of the language employed, of which Congress was undoubtedly aware, the amendment of 1938 (Sec. 402) not only impliedly approved this construction of its language but strengthened it by adding words which leave no doubt of its intention to free interstate commerce of any food if it consists "in whole or in part of any filthy, putrid or decomposed substance". The added clause "or if it is otherwise unfit for food" is in the disjunctive and does not condition, qualify, or obscure the plain meaning of the whole sentence when considered in its context. *United States v. 184 Barrels Dried Whole Eggs*, 53 F. Supp. 625. This view is supported by the general purpose of the amendment to extend the range of control over impure and adulterated food and drugs moving in interstate commerce. *United States v. Dotterweich*, 320 U. S. 277.

According to the conclusive findings of the trial court each carton of fish seized consisted in part of fish in a decomposed state and it was necessary to thaw the fish in each carton in order to separate the decomposed substance from the wholesome part. It is thus clear that the product in question comes within the interdiction of the Act and the judgment of the trial court is reversed.

---

**UNITED STATES v. TWO BAGS, MORE OR LESS, EACH  
CONTAINING 110 POUNDS, POPPY SEEDS, ARCO  
PRODUCTS COMPANY, CLAIMANT**

United States Circuit Court of Appeals for the Sixth Circuit. No. 9852.  
Decided January 31, 1945. 147 F. 2d 123.  
Reversing 54 F. Supp. 706. See page 78.

The lower court held that the addition of charcoal pigment to white poppy seeds so that they resembled more expensive seeds, the product then being shipped to jobbers truthfully labeled, tended to conceal inferiority and make the product appear better than it was as far as consumers, but not jobbers, were concerned. The article, having been found to be adulterated under Subsections (b) (3) and (b) (4) of Section 402 insofar as consumers were concerned, should have been condemned.

Section 402 (b), Federal Food, Drug, and Cosmetic Act.



The Federal Food, Drug, and Cosmetic Act was not intended to be confined to the requirement of truthful labeling of goods.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

"Economic adulteration" could not be avoided by the limited effect which the district court gave to the express language of the Act.

Section 402 (b), Federal Food, Drug, and Cosmetic Act.

From its inception to its last amendment, the Food and Drugs Act was not designed primarily for the protection of merchants and traders, but was intended to protect the consuming public.

Title, Federal Food, Drug, and Cosmetic Act.

Congress has ample power to keep the channels of interstate commerce free from the transportation of illicit or harmful articles.

Sections 304 (a), 901, Federal Food, Drug, and Cosmetic Act.

Whether dealers or traders in articles are deceived is not the material question. The appropriate inquiry is whether the ultimate purchaser will be misled.

Title, Federal Food, Drug, and Cosmetic Act.

The Act must be construed liberally to effectuate its remedial purposes.

Title, Federal Food, Drug, and Cosmetic Act.

The true test was whether the article proceeded against was adulterated when shipped and while in interstate commerce.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The Act could not be enforced if the Government were compelled to establish a wrongful intent on the part of those who ship prohibited articles in interstate commerce.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Fred H. Mandel, Cleveland, Ohio (Tom C. Clark, Washington, D. C., Don C. Miller, Cleveland, Ohio, and James B. Goding, Atty., Federal Security Agency, were with him on the brief); Vincent A. Kleinfeld, Washington, D. C., of counsel; for appellant.

George X. Levine, New York, N. Y., for appellee.

Before HAMILTON, MARTIN and McALLISTER, Circuit Judges.

*[Libel Dismissed by Trial Court]*

MARTIN, Circuit Judge: The District Court dismissed a complaint filed as a libel *in rem* on information by the United States Attorney for the Northern District of Ohio for the seizure and condemnation of two bags, more or less, each containing 110 pounds of poppy seeds, shipped in interstate commerce from Brooklyn, New York, to Cleveland, Ohio; and ordered the seized goods returned to the owner. The libel was grounded upon averments that the poppy seeds were adulterated within the meaning of Section 402 (b) (3) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. A., Section 342 (b) (3)], which provides:

"A food shall be deemed to be adulterated—(3) if damage or inferiority has been concealed in any manner;"

and of Section 402 (b) (4) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. A., Section 342 (b) (4)], which provides: "A food shall be deemed to be adulterated—(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

Upon the evidence in the case, the district court found that the owner and claimant of the seized merchandise, the Arco Products Company of Brooklyn, New York, had shipped the poppy seeds in interstate commerce to jobbers, and not to ultimate consumers; that the poppy seeds were intended to be used as food and components of food for human consumption; and prior to shipment had been colored by charcoal pigment



made from burnt poppy seeds. It was found further that these poppy seeds, products of British India, were naturally of a whitish color and, when uncolored, had a market value ranging from ten to eleven cents a pound; but, when artificially colored, they had a market value of about twenty-two-and-a-half cents a pound. There was a marked difference in the market value of these British India poppy seeds, on the one hand, and Dutch blue and Turkish grey poppy seeds, on the other. The latter were much more expensive. The coloring of the Dutch and Turkish seeds was natural and they were somewhat larger than the British India, white poppy seeds.

The Dutch and Turkish seeds have been used extensively—indeed, almost exclusively—for decorative and flavoring purposes in the manufacturing of bread, rolls and other baked goods. After the United States became involved in World War II, the Dutch blue and Turkish grey poppy seeds were hardly procurable at all, making the British India product the only available poppy seeds on the market.

The Arco Products Company devised a method of coloring British India white poppy seeds with charcoal pigment, made from burnt poppy seeds; so that, as found by the district court, the

“British India white poppy seeds resembled in color and shape the genuine Dutch blue and Turkish grey poppy seeds, except that the artificially colored seeds were of a size smaller, and had a more uniformly black or dark grey shade than the genuine Dutch blue and Turkish grey poppy seeds respectively.”

The court found further that there is little, if any, difference in flavor, and no difference in food value of the naturally and artificially colored seeds; and that a person inexperienced in such matters would fail to notice the difference between the Dutch blue or Turkish grey poppy seeds and the artificially colored British India white poppy seeds. It was found that the purpose of the Arco Products Company in the coloration was to impart “eye appeal” to the white poppy seeds which were shipped by it in interstate commerce, to jobbers only, in bags labeled: “Produce of British India. Artificially colored with vegetable colors.”

Pointing out that jobbers in the trade were well aware of the difference between the poppy seeds, whether in their natural

state or artificially colored, and could not have been deceived by the artificial coloring, particularly where the seeds were shipped in bags with informative labels, the district court concluded its findings of fact with this important finding:

“The addition of charcoal pigment made from burnt poppy seeds to the British India white poppy seeds tended to conceal the price inferiority of said poppy seeds in the hands of the ultimate consumers, but not the jobbers, and tended to make them appear better and of greater value than they were in that the inferiority thereof had been concealed by addition of substance, charcoal, and that the substance, charcoal, had been added thereto so as to make it appear better or of greater value than it was.”

This last finding, as was each of the other findings of the court, was supported by substantial evidence.

In a memorandum opinion, the district judge stated that, on all the testimony, the questions presented were whether the article is adulterated within the meaning of Section 342 (b) (3), Title 21, U. S. C. A., in that inferiority has been concealed by addition of charcoal; and whether the article is adulterated within the meaning of Section 342 (b) (4), 21 U. S. C. A., in that charcoal has been added thereto so as to make the article appear better or of greater value than it is. He thus answered the questions which he put:

“If those questions are answered with reference to retailers and consumers they would have to be answered in the affirmative. If, however, they are answered with reference to jobbers, the evidence convinces the court that they should have a negative answer. In spite of the fact that the British India seeds on close examination reveal a smaller size and a more uniformly black or very dark grey shade and that Dutch blue and Turkish seeds are somewhat larger and contain variegated shades of color, still a cursory look at the seeds would reveal no difference. Anyone inexperienced in such matters would fail to note the difference between the naturally dark seeds and the artificially colored seeds. While the difference in flavor, if any, is slight and there is no difference in food value, there is nevertheless a difference in commercial value or price, and the coloring of the white seeds does conceal that price inferiority and does make the white seeds appear better or of greater value than they are.”

Inasmuch as jobbers, who were the consignees, were well aware of the distinctions



between the seeds, the district court reasoned that

"the legality of the product must be tested by its condition at the time of seizure and not by what its condition might be after it has passed beyond interstate commerce channels or been transposed from the packages in which it was shipped or changed in form or content;"

that

"if the public is to be protected against the sale of colored poppy seeds unlabeled or improperly labeled it will require state law and state administration;"

that

"if the interstate shipment is not a 'palming off' of something inferior it is not in violation of the statute merely because it has a potentiality of deception;"

and that it having been found that the seeds involved in the case were labeled and billed for what they actually were, the court should not treat them as contrabrand

"merely because of the possibility that they might be used subsequently to deceive."

[Seeds Should Be Condemned When Adulterated Insofar as Consumers Are Concerned]

We are unable to agree with the reasoning of the district court; and think that, the article having been found to be adulterated within the meaning of Sections 342 (b) (3) and 342 (b) (4), insofar as consumers are concerned, the seized seeds should have been condemned under the Federal Food, Drug and Cosmetic Act. To set up deception of jobbers as the criterion for the determination of the issue of condemnation was, in our judgment, clearly erroneous. The express language of the pertinent provisions of the Act of Congress is reasonably susceptible of no such narrow interpretation. The district court found as a fact that the inferiority of the food had been concealed; that an added substance had made it appear better or of greater value than it is insofar as the ultimate consumer was affected; and that an inexperienced person would fail to detect the difference between the natural Dutch blue or Turkish grey poppy seeds and the artificially colored British India white seeds, shipped in interstate commerce by the Arco Products Company.

[Supreme Court's Holdings]

In construing the original Pure Food and Drugs Act of 1906, the Supreme Court pointed out that the statute rests upon the power of Congress to regulate interstate

commerce; that no trade can be carried on between the states to which this power does not extend; that it is complete in itself, subject to no limitations except those found in the Federal Constitution; and that it must be remembered that the Act deals with illicit articles, which the law seeks to keep out of commerce and to punish, along with the shipper of them, because the articles are debased by adulteration. *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57.

In *Carolene Products Company v. United States of America*, — U. S. —, decided November 6, 1944, the Supreme Court said:

"When Congress exercises a delegated power such as that over interstate commerce, the methods which it employs to carry out its purposes are beyond attack without a clear and convincing showing that there is no rational basis for the legislation; that it is an arbitrary fiat."

The right both of a state and of Congress to go beyond the protection of the public by prohibition of false labeling or branding of goods to more adequate protection by the prohibition of a substituted food product has been held by the highest court to be within the legislative power. *United States v. Carolene Products Co.*, 304 U. S. 144, 151; *Hebe Co. v. Shaw*, 248 U. S. 297, 302, 303. Moreover, the Supreme Court has declared that the Food and Drugs Act was not intended to be confined to the requirement of truthful labeling of goods, but that the statute was intended to protect the public against adulteration of articles of food by the addition of substances deleterious to the health of consumers. *United States v. Coca Cola Co.*, 241 U. S. 265, 277, 278. Consult to same effect *Commonwealth of Pennsylvania v. Hettinger*, 152 Pa. Super. 242, 31 Atl. (2d) 599.

In *Federal Securities Administrator v. Quaker Oats Co.*, 318 U. S. 218, 230, the Chief Justice leaves no doubt that, from its text and legislative history, the purpose of the present Federal Food, Drug, and Cosmetic Act was not confined to a mere requirement of truthful and informative labeling, which had been found inadequate to protect the consumer from " 'economic adulteration,' by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold."



*U. S. v. Two Bags Poppy Seeds**[Consumer Unaware of Substitution]*

Upon the principles of that case, "economic adulteration" in contravention of the Act could not be avoided in the instant case by the limited effect which the district court gave to the express language of the Act. Here, the consumer would be unaware that less expensive ingredients had been substituted and that the article was inferior to that which he expected to receive when making his purchase. The fact that the substituted article was not deleterious is immaterial. From its inception, to its last amendment, the Pure Food and Drugs Act was not designed primarily for the protection of merchants and traders; but was intended to protect the consuming public.

*[Fact That Goods Are Not Injurious Is Immaterial]*

In *Carolene Products Company v. United States of America*, 140 F. (2d) 61, 65 (C. C. A. 4), Judge Dobie declared:

"Congress may with constitutional impunity bar from interstate commerce goods which may be the subject of a fraudulent sale, although the goods themselves may not be injurious."

On appeal of the case, this principle was upheld and the judgment was affirmed. *Carolene Products Company v. United States of America*, *supra*.

*[Purpose of Act Is To Protect Consumer]*

It would seem clear beyond controversy that Congress has ample power to keep the channels of interstate commerce free from the transportation of illicit or harmful articles; and that the object of the Food and Drugs Act is to prevent the misuse of the facilities of interstate commerce in either conveying to or placing before the consumer misbranded or adulterated articles of medicine or food; and, by later amendment, cosmetics. *McDermott v. Wisconsin*, 228 U. S. 115, 128, 131.

Whether dealers or traders in articles are deceived is not the material question. The appropriate inquiry is whether the ultimate purchaser will be misled. *Libby, McNeill & Libby v. United States*, 210 Fed. 148 (C. C. A. 4). Compare *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos*, 53 F. Supp. 746, 752. As was said by the Supreme Court, in *United States v. Antikamnia Co.*, 231 U. S. 654, 665:

"The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it."

See also *United States v. Schider*, 246 U. S. 519, 522; *United States v. Research Laboratories*, 126 F. (2d) 42, 45 (C. C. A. 9).

In *United States v. Dotterweich*, 320 U. S. 277, 280, the Supreme Court gave recent expression to the view that the act under consideration should be liberally construed, so as to effectuate its purpose:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128."

The erroneous conclusion reached by the district court seems to stem from confusion concerning the primary purpose of the Act, which, as has been demonstrated, is not protection of jobbers, dealers, or traders, but protection of the ultimate consumer. The court failed to apply correctly the principle that the true test is whether the article was adulterated when shipped and while in interstate commerce. Only six cases were cited in the opinion below: *United States v. 492 Cases, More or Less, of Orange Juice, Each Case Containing Two One-Gallon Jugs*, 20 F. Supp. 520, affirmed in *United States v. Nesbitt Fruit Products, Inc.*, 96 F. (2d) 972 (C. C. A. 5); *United States v. Lexington Mill Co.*, 232 U. S. 399; *United States v. Great Atlantic and Pacific Tea Co.*, 92 F. (2d) 610 (C. C. A. 2); *Austin v. Tennessee*, 179 U. S. 343; *Sonneborn Bros. v. Cureton*, 262 U. S. 506; *Schechter Corp. v. United States*, 295 U. S. 495 (Syllabus 3, 4). We think the district court misapplied these authorities. The opinion states that "it seems to this court that this case falls within the principle announced in *U. S. v. 492 Cases Orange Juice, supra*; *U. S. v. Nesbitt Fruit Products*, 96 F. (2d) 972; and in *U. S. v. Lexington Mill & Elevator Co.*, 232 U. S. 399."

*[Orange Juice Case Distinguished]*

The first two citations refer to the same case, which might be called the "orange juice" case, in which the action of a district court in dismissing a libel was affirmed.



The opinion on appeal makes plain the factual differentiation from the case at bar. The Court of Appeals said [96 F. (2d) 973]:

"The retailer who buys these jugs of Nesbitt's product, which are shipped in interstate commerce, does not buy them as orange juice but as a mixture whose ingredients are disclosed from which he may prepare a beverage. In practice the jug is placed upon the retailer's counter with the full label in plain view, and the dilution is made in the customer's presence."

But Judge Foster even dissented from the majority view that the consumer would not be deceived, and said:

"I consider the label tends to deceive and mislead the ultimate purchaser and therefore the article is misbranded within the prohibition of the Food and Drugs Act."

In the orange juice case, there was no finding of fact that the ultimate consumer would be misled. In the instant case, the contrary is true. In the orange juice case, the adulteration occurred after the product was no longer in interstate commerce; in the instant case the adulteration occurred before the goods were placed in interstate commerce and existed at the time of seizure.

[*Lexington Mill Case Distinguished*]

The other case which the district court considered controlling, *United States v. Lexington Mill Co.*, 232 U. S. 399, 409, expressly recognized that the primary purpose of Congress in enacting the Food and Drugs Act was to prevent injury to the public health by the sale and transportation in interstate commerce of misbranded and adulterated foods; and that

"if this purpose has been effected by plain and unambiguous language, and the act is within the power of Congress, the only duty of the court is to give it effect according to its terms."

On the facts of the case, the bleaching of the flour in the manner employed was not deemed deceptive; while, in the instant case, the district court found that the inferiority of the article shipped in interstate commerce was concealed from the consumer, and the article was made to appear to him better or of greater value than it is.

[*Other Cases Irrelevant*]

In our judgment, the other four citations

in the opinion of the district court are irrelevant in the context.

[*Intended Use of Adulterated Food Immaterial*]

The Circuit Court of Appeals for the Second Circuit has held that the intended use to which adulterated food is to be put, after it has been shipped in interstate commerce, is immaterial on the issue of the government's right to forfeit the food because of the interstate commerce shipment. *United States v. 52 Drums Maple Syrup*, 110 F. (2d) 914. See also *Union Dairy Co. v. United States*, 250 Fed. 231, 233 (C. C. A. 7).

[*Wrongful Intent of Shipper Not Requisite*]

As was declared in *United States v. Thirteen Crates of Frozen Eggs*, 215 Fed. 584, 585 (C. C. A. 2), the Food and Drugs Act could not be enforced if the government is compelled to establish a wrongful intent on the part of those who ship prohibited articles in interstate commerce. It is enough that the articles are prohibited; and all that is necessary to be shown to justify condemnation is that the adulterated article of food has been transported in interstate commerce.

[*Bred Spred Case Distinguished*]

Appellee stresses *United States v. Ten Cases, More or Less, Bred Spred*, 49 F. (2d) 87 (C. C. A. 8). In that case, there was no showing of the inferiority of the food product sought to be condemned. Here, the poppy seeds shipped by the appellee were of less commercial or market value; were of smaller size; and were artificially colored so that, as found by the district court, "a person inexperienced in such matters would fail to notice the difference between the Dutch blue or Turkish grey poppy seeds and the artificially colored British India white poppy seeds." The Eighth Circuit decision, therefore, gainsays nothing which we have said in this opinion, and, moreover, adheres to the doctrine that the primary purpose of the Food and Drugs Act is to prevent injury to the public health by the transportation in interstate commerce of misbranded and adulterated foods.

[*Judgment Reversed and Condemnation Directed*]

The judgment of the district court is reversed, with direction that a decree of condemnation be entered in conformity with the prayer of the libel *in rem* filed by the United States.



UNITED STATES v. FIVE CASES, More or Less, Each Containing One Demijohn, 5-gallon Size, 9 Cases, More or Less, Each Containing 6 Bottles One-Half Gallon Size, and 13 Cases, More or Less, Each Containing 12 Bottles, One-Half Gallon Size, of "Capon Springs Water"

United States District Court for the Southern District of New York. Ad. 127-241. Dated February 13, 1945. 62 F. Supp. 736. Reversed, 156 F. 2d 493. See page 187.

A decision by the Federal Trade Commission is binding on the Government in a seizure action against mineral water alleged to be misbranded under the Federal Food, Drug, and Cosmetic Act by reason of false and misleading therapeutic claims in the label of the water.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

In a seizure action, it was held that the Federal Trade Commission, in simply placing its disapproval upon a certain claim, had thereby given its approval to other claims made on behalf of the product involved in the seizure action.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Since the underlying issue in the seizure action and in the Federal Trade Commission proceeding was the same, the adjudication in the Commission proceedings was determinative of the issue in the seizure suit.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

A decision for the claimant in a prior seizure action brought under the Food and Drugs Act of 1906 against mineral water, alleging misbranding because of false and fraudulent therapeutic claims, is *res judicata* in a seizure action under the present act alleging misbranding under Section 502 (a).

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

James B. M. McNally, U. S. Attorney for the District of New York; Stanley H. Lowell, Assistant U. S. Attorney and James B. Goding, Attorney, Federal Security Agency, of counsel; for libelant.

William M. Kilcullen, Proctor for Andrew P. St. Thomas and Capon Spring Water Company and Louis L. Austin and Virginia H. Austin, Co-Partners, doing business under the firm name and style of Capon Springs and Farms, for claimant.

[Confiscation of Capon Springs Water Sought]

EDWARD A. CONGER, District Judge: Libelant, the United States of America, seeks herein to confiscate a certain quantity of Capon Springs Water which it has seized.

[Misbranding of Water Charged]

The libel states that this water, shipped in interstate commerce was misbranded in that, in violation of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. Sect. 352 (a)), the label on the bottles containing the water contained statements which were false and misleading.

[Misleading Statements Charged]

The following statements appearing on

the labels are alleged to be false and misleading and to constitute misbranding:

"Rebuilds as it Cleanses \* \* \*

"The Indians Called It Ca-Ca-Pa-On—'Health Water' \* \* \*

"Known to physicians as alkaline, because it contains by nature those elements needed to counteract acidity."

"\* \* \* beneficial in restoring the normal activity of the kidneys and bowels."

"Use according To A Natural Law of Health \* \* \*

"For the best results \* \* \* drink 2 glasses on rising, 2 more during the morning, 2 during the afternoon and 1 or 2 at night \* \* \*

The libel after alleging that these statements are false and misleading continues—"said articles when so consumed will not



exert such effect nor produce effects essentially different from those produced by the consumption of similar quantities of ordinary drinking water."

*[Amended Answer Denies Misbranding]*

The parties responsible for the bottling and shipment of the water have appeared and answered herein.

The amended answer herein denies any misbranding.

*[Interstate Shipment Not Denied]*

The fact that the waters were shipped in interstate commerce is not denied.

*[Res Judicata Defense]*

The First and Second defense in the amended answer set up the defense of *res judicata*. These defenses concern two proceedings heretofore had in connection with Capon Springs Water. There can be no question but that the water involved in those proceedings is the same water with which we are concerned here.

By these defenses, claimants allege that the truth of the statements on the label herein have been finally determined in claimants' favor in two actions heretofore had and that said prior final decisions are *res judicata* determinative of the issues herein as to the truth or falsity of said statements.

The second or later proceeding (second defense) was brought on or about March 3, 1936 before the Federal Trade Commission. The Respondents in that case were the same Respondents, their privies or predecessors in title now before this court.

The proceeding was commenced pursuant to the provision of an Act of Congress creating a Federal Trade Commission (approved September 26, 1914) (15 U. S. C. A. Sect. 55 (a)). The gravamen of the complaint in that proceeding was that Respondents were guilty of falsely advertising their product in booklets, circulars and other written matter.

*[Statutory Definition of False Advertisement Quoted]*

The pertinent section of 15 U. S. C. A. Sect. 55 (a) reads as follows:

"The term 'false advertisement' means an advertisement, other than labeling, which is misleading in a material respect;  
\* \* \*

*[Allegations Set Out]*

The precise charge is set forth in Paragraph Two and Paragraph Three of the

libel. Paragraph Two in part reads as follows:

"Respondents, in the course and conduct of their business as aforesaid, distribute and circulate, among prospective purchasers of their said water, booklets, leaflets, circulars and other written matter which contain many statements concerning the curative qualities of respondents' said water. Many of said statements are purportedly made by doctors and laymen, and the remainder by the respondent. In said booklets, leaflets, circulars, and other written matter, respondents falsely represent and imply that said water will cure, or is beneficial in the treatment of, many of the diseases, ailments, afflictions, and conditions which may be present or exist in the human body.

"Among the diseases, ailments, afflictions, and conditions named by the respondents in their said booklets, leaflets, circulars, and other written matter, so distributed and circulated among prospective purchasers of their said water, as diseases, ailments, afflictions, and conditions which their said water will cure, or is beneficial in the treatment of, are the following \* \* \*"  
Then follows a long list of diseases too numerous to repeat, among which are kidney troubles, kidney pains, nephritis, bladder trouble, catarrhal affections of the stomach, hyperacidity, constipation, irregular bowels."

Paragraph Three reads as follows:

"Respondents, in said booklets, leaflets, circulars, and other written matter, so distributed and circulated among prospective purchasers of their said water, falsely represent and imply that their said water acts 'like magic'; 'cures almost everything'; 'aids digestion'; 'restores energy'; is 'beneficial to general health'; 'keeps you fit'; 'keeps you well'; that it has 'eliminated tired feeling'; 'maintains healthy digestive tract'; that it has 'improved hearing'; is 'indispensable to health'; 'acts as a natural tonic'; 'restores mental alertness and vigor'; 'will help every living thing'; assures 'All year round health and long life'; 'supplies every one of the 16 elements in body'; and contains 'valuable medicinal properties'."

"In truth and in fact respondents' said water not only has not acted and does not act like magic, but has not acted and does not act at all on the human body in any different manner than does any pure, potable water, nor does it contain any elements or medicinal properties in sufficient quantities to render it different from, or any of greater benefit than, any pure, potable water, and its use



*U. S. v. Five Cases et al. "Capon Springs Water"*

has not resulted and does not result in the benefits claimed for it by said respondents as above set out."

*[FTC Trial and Findings]*

The above allegations were put in issue by the answer of respondents. The issues were tried before a trial examiner, who made his report upon the facts to Federal Trade Commission, from which the Commission made its "Findings as to the Facts and Conclusions."

*[Expert Testimony as to Therapeutic Value of Water]*

A great deal of testimony was taken before the trial examiner. The real issue was as to the therapeutic value of this water. The Commission had as witnesses several chemists and three physicians. The conclusions of these experts was that this water had no special chemical value; that it had no therapeutic value; that it would not cure or benefit the specific diseases mentioned in the complaint; that the mineral content of this water was no greater than that of ordinary tap water; that this water would have no more effect than any good drinking water.

Respondent put in testimony of four physicians who testified among other things that the water did possess therapeutic value and qualities; that it possessed therapeutic values different from other pure potable waters. Each testified that he prescribed this water in cases of illness and disease and told of the curative and beneficial effect by its use.

There was taken in all about 600 pages of testimony.

*[Extracts from Respondent's Advertisements Quoted]*

Some of the literature used by Respondent in advertising its product was put in evidence. It will not be necessary to go into the various claims made in these documents. However, a few extracts from one (Ex. 1) are pertinent. This is a small leaflet entitled "Things You Will Observe About Capon Springs Water." I quote some extracts therefrom:

"REFRESHES"

\* \* \*

"CLEANSES"

\* \* \* 5. It has prompt action on the kidneys. Capon cleanses your blood of acid and toxic poisons."

"REBUILDS"

"6. It regulates the bowels. Capon restores their normal peristaltic action (the eliminative urge)."

"7. It acts as a natural tonic. Capon supplies every one of the sixteen elements in your body."

"WHY THE INDIANS CALLED IT CA-CA-PA-ON — 'HEALING WATERS'"

\* \* \*

"Capon water is known to physicians as alkaline \* \* \*"

*[Preceding Extracts Basis of Commission's Charge of False Advertising]*

These are extracts from one of the pamphlets on which the Commission based its charge of false advertising. The label which is under fire here was put in evidence.

*[Statements Set Forth in Trial Examiner's Findings]*

The trial examiner in his Findings has set forth most of the statements thereon under the heading: "Respondent's Representations, concerning the Efficiency of Capon Water."

*[Finding of Commission]*

Notwithstanding the broadness of the charges and the plethora of evidence, the Commission simply contented itself with a finding against Respondent, "that the use of Capon Water *alone* either externally or internally will not cure kidney troubles" . . . (Then follows the long list of diseases which the Commission claims Respondent advertised Capon Water would cure or be beneficial in the treatment thereof.)

*[Commission's Order]*

This was the only respect in which the Commission found that Respondent by its advertising had violated the provision of the Federal Trade Commission Act. As a result thereof an order was made by the Commission that Respondent in connection with the offer for sale and distribution of its water cease and desist from representing directly or by implication "that the use of the said water alone, either externally or internally will cure kidney troubles—" etc. This record indicates that this order was complied with.

*[Testimony Before Commission Similar to Testimony Before Court]*

It should be noted that the testimony taken before the Commission was of the same nature as that before me. Most of it was by experts (doctors and chemists). It all had to do with the chemical properties and therapeutic value of this water. The experts' testimony taken before the Commission might very well have been substituted for and used in the case before me.



[*FTC Order Affirmed*]

The order of the Federal Trade Commission was affirmed by the United States Circuit Court of Appeals for the Third Circuit (*Capon Water Co., et al. v. Federal Trade Commission*, 107 Fed. (2) 516.)

[*Proceeding Before Commission as  
 Defense to Issue*]

I have gone to some length into this proceeding before the Federal Trade Commission because I am of the opinion that it is the real serious defense to the issue here.

[*Libelant Bound by FTC Decision*]

I have come to the conclusion that the decision of the Federal Trade Commission binds the Libelant here.

[*Proceeding Before Commission Concerned  
 with Therapeutic Value of Water*]

In the proceeding before the Commission the litigated question was the chemical and therapeutic value of this water. The Commission had before it the printed material advertising Capon Water. In it were many and rather extravagant statements extolling the virtue and healing property of the water which included the claim that the consumption of this water would cure or be beneficial in the treatment of most of the ills and sicknesses that men and women are afflicted with.

[*Commission Condemned Only Claim that  
 Water Alone Would Cure*]

Yet, after a lengthy trial, the Commission simply placed its condemnation upon the claim that *this water alone would cure*.

[*Failure of Commission To Condemn  
 Other Claims*]

It gave its approval, by a failure to condemn all the other claims which included those mentioned in Exhibit 1, and heretofore set forth.

[*Similar Statements Contended by Govern-  
 ment To Be Misleading*]

I referred to those statements particularly because they are identical with or approximate the statements on the label which the Government contends are false and misleading—

"in that said statements represent and suggest that the article of drug when consumed according to directions will rebuild the body while cleansing it of waste matter, will exert an alkaline effect in the body and counteract acid conditions, will serve to restore improperly functioning kidneys and bowels to their normal activ-

ity and will exert benefits to health greatly in excess of those derived from the consumption of ordinary drinking water." (Paragraph V of the Libel).

[*Exact Issue Tried Before Commission*]

This is exactly the issue that was tried before the Commission and decided by it as I have pointed out above.

[*Ruling on Pamphlet Statements Bars Action  
 Against Label Statements*]

The Government contends that proceedings before the Commission are not a bar to the successful prosecution of this action, because the label was not passed on by the Commission. I think it is correct that the label with the statements thereon was not specifically passed on. However, may it be said that certain statements in the pamphlets may be used and are not false and misleading while the same statements used on the label may not be used and are false and misleading. I think not.

[*Adjudication in Proceeding Before Com-  
 mission Determinative in Immediate  
 Action*]

As I see it the underlying issue in this action and in the proceeding before the Commission is the same. That being so, the adjudication in the proceeding before the Commission is determinative of the issue here. *United States v. Willard Tablet Co.*, 141 F. (2) 141; *George H. Lee Co. v. Federal Trade Commission*, 113 F. (2) 583.

[*Difference in Complaints and Remedies  
 Sought Immaterial*]

The fact that in one proceeding we have the Federal Trade Commission as the complainant and in this case we have the United States of America does not alter the situation, neither does the fact that different remedies are sought in each proceeding affect the result. *United States v. Willard Tablet Co.*, *supra*; *George H. Lee Co. v. Federal Trade Commission*, *supra*.

[*Another Libel Proceeding as Basis for  
 Res Judicata*]

My opinion is fortified by another adjudication as to this same water. *United States v. Ninety-Four Dozen, more or less, Half-Gallon Bottles Capon Springs Water*, 48 F. (2) 378. This adjudication is alleged as *res judicata* to this action and is the first defense in the amended answer herein.

In that proceeding the United States of



America by a libel sought to condemn 94 cases more or less, half-gallon bottles of Capon Springs Water. The prosecution was based on the Food and Drugs Act (21 U. S. C. A. 1 *et seq.*)

This action was tried in the United States Eastern District of Pennsylvania. The complaint in that case was that there was a misbranding on the label. In his opinion Judge Dickinson, who tried the case, set forth the charge as follows:

"It is charged that Capon Springs Water is marketed under a label which described it to be 'Healing Water', thereby implying that the drinking of it will have curative and therapeutic results, when in fact the water is more accurately described as drinking water, having only the properties of what might be called ordinary spring water."

The label which was objected to was in form as follows:

"'Capon Springs' Water known to the Catauaba Indians as 'Ca-Ca-Pa-On' Healing Water.

'2 Quarts Net—Bottled at the Springs. (Then follows an analysis in type too small to be conveniently read.)

'Natural Mineral Spring Water Famous for Two Centuries. Capon Water Co., Capon Springs, W. Va.'"

Judge Dickinson in his opinion stated, "We see nothing in the label in this case which would justify a finding that it was fraudulent". In that action the libel was dismissed. Affirmed by the Circuit Court of Appeals for the Third Circuit, 51 F. (2) 913.

*[Adjudication Determinative of One Charge of Misbranding]*

If the adjudication in this case is not determinative of the entire issue here it is at least determinative of the charge of misbranding as applied to the phrase on the label. "The Indians Called it Ca-Ca-Pa-On Health Water." The fact that in this one case [we] have the words "*Healing Water*" and in the other "*Health Water*" has no significance. The words are synonymous.

*[Libel Dismissed]*

For the reasons which I have given above, I find that the libel should be dismissed.

Settle decree on notice.

---

**LIBBY, McNEILL & LIBBY v. UNITED STATES**

United States Circuit Court of Appeals for the Second Circuit. No. 199.

Decided March 8, 1945. 148 F. 2d 71.

Affirming 55 F. Supp. 725. See page 115.

The product proceeded against complied with the definition and standard of identity for tomato catsup except that it contained benzoate of soda, not permitted by the standard. It was labeled as catsup with preservative, and was sold, truthfully labeled, primarily to hotels and restaurants. The product purported to be tomato catsup, and the decree of condemnation entered by the trial court, based on the failure of the product to comply with the standard because of the presence of benzoate of soda, should be affirmed.

Sections 304 (a), 401, 403 (g), Federal Food, Drug, and Cosmetic Act.

If producers of food products, by adding to the common name of a standardized food mere words of qualification or description, may escape the regulation, then the fixing of a standard for commonly known foods becomes utterly futile in protecting the consuming public.

Sections 401, 403 (g), 403 (k), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act was not confined to a requirement of truthful and informative labeling.

Title, Federal Food, Drug, and Cosmetic Act.



A product which looked, tasted, and smelled like catsup, which was sold and invoiced as catsup without reference to the preservative not permitted by the definition and standard of identity for catsup, and which was substituted for catsup on the tables of low priced restaurants, purported to be catsup.

Sections 401, 403 (g), 403 (k), Federal Food, Drug, and Cosmetic Act.

Congress may prohibit the shipment in interstate commerce of non-deleterious substances.

Title, Federal Food, Drug, and Cosmetic Act.

The appropriate inquiry is whether the ultimate purchaser will be misled.

Title, Federal Food, Drug, and Cosmetic Act.

Transactions subsequent to the interstate shipment of a food have a bearing on whether a definition and standard of identity for a food is avoided.

Sections 304 (a), 401, Federal Food, Drug, and Cosmetic Act.

Breed, Abbott and Morgan; Michael F. Markel, Lyndle W. Hess, of counsel; for appellant.

Tom C. Clark, Assistant Attorney General; T. Vincent Quinn, U. S. Attorney, and Morris K. Siegel, Assistant U. S. Attorney; Vincent A. Kleinfeld, Attorney, Department of Justice, and Arthur A. Dickerman, Attorney, Federal Security Agency, of counsel; for appellee.

Before HUTCHESON, SIMONS, and CLARK, Circuit Judges.

[*Facts of Case*]

SIMONS, Circuit Judge: The Federal Security Administrator charged with enforcement of the Federal Food, Drug and Cosmetic Act, acting under authority of § 401 [21 U. S. C. §§ 343 (g), (k), 341] promulgated regulations establishing a definition and standard of identity for tomato catsup. The appellant produced and shipped in interstate commerce the condemned food product which concededly does not conform to the standard in that it contains sodium benzoate, a substance not permitted as an ingredient. The government's libel charged that the food was misbranded in violation of § 403 (g), and this the appellant, as claimant, denies on the ground that the product was not sold as tomato catsup but as "tomato catsup with preservative", the labels upon the containers specifically declaring that the product does not conform to government standard for catsup, and contains 1/10 of 1% benzoate of soda.

Sections 403 (g), (k), of the Act declare when a food is deemed to be misbranded, and insofar as the provisions are pertinent, they are printed in the margin.<sup>1</sup> The sole contention urged upon appeal is that the seized product being truthfully labeled, not deceptively packaged, and sold under a name accurately descriptive of its composition, is not misbranded within the meaning of § 403 (g), because of the presence in the food of the sodium benzoate. It is urged that the branding of a product as relating to its characteristics and composition, is the sole basis for determining whether it is misbranded, and that the section does not have the effect, nor was it intended by Congress to have the effect of excluding any product from interstate commerce when it is sold for what it is. As a supplementary proposition, it is urged that misbranding of the specific product seized is not to be established by designations of identical products applied to them not by their producer but by retail dealers to their customers.

<sup>1</sup> "Sec. 403: A food shall be deemed to be misbranded—

"(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the

definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food."

"(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: \* \* \*."



As produced and shipped by the appellant, the condemned food is packed in No. 10 cans with the described labels thereon. It is catsup as defined by the Administrator, to which there has been added the minute quantity of sodium benzoate as a chemical preservative. This preservative is harmless, is commonly used in other foods, including oleomargarine, preserves, and jellies, and does not affect the viscosity, taste, smell, or appearance of the catsup. It is explained that there is a wide variation in the degree of concentration of catsup, and a well-established practice in the trade to call a catsup of the higher concentration "fancy", and that of the lower concentration "standard". The difference in specific gravity between the two products is due to the difference in the quantity of added sugar, and the amount of added sugar is determined by the quantity of vinegar added. Catsup is rendered virtually sterile by heat processing, but will spoil after opening unless it contains a preserving agent. Vinegar, sugar, and salt, in combination, are good preserving agents when added in sufficiently large quantities. The amounts required by the standard are relatively small because added only as seasoning ingredients, so it had been the practice in the industry, quite generally, up to 1940, to add sodium benzoate to a lower concentration so as to give it a keeping quality comparable to catsup preserved by added sugar and vinegar.

While fancy catsup is packed in bottles for table use, standard catsup is packed in No. 10 cans and sold primarily to hotels, restaurants, and similar establishments, although standard catsup, to some extent, is used as table catsup in low priced restaurants. Generally, however, standard catsup is used in cooking and in the preparation of sauces. It costs about 25% less than table catsup because it contains less sugar which is a costly ingredient, and is in response to a demand for a less expensive product.

*[Finding of District Court; Contention of Appellant]*

The district court found the product under seizure to conform in all respects to the definition and standard promulgated by the Administrator, except for the addition of

the small quantity of benzoate of soda, but held that it purported to be catsup, and so, since it did not conform to the standard, was misbranded. Decision therefore turns upon the meaning of the word "purport" as used in § 403 (g). The appellant contends that the label is controlling, that its product does not thereby purport to be catsup, even though it conforms in all respects to the standard, except for the added ingredient. It is a specific article, namely, tomato catsup with preservative, and since its label truthfully so indicates, there is no misbranding. The label may be disregarded only if it is assumed that § 403 (g) expresses an intent on the part of the Congress to outlaw the manufacture of foods not conforming to applicable standards which, but for the standard, would be sold under the same common and usual name.

*[Standard Futile If Avoided by Addition of Qualifying Words]*

It is impossible for us, in the light of controlling authority, to accept the contention. The condemned food is tomato catsup, and purports to be tomato catsup.<sup>2</sup> If producers of food products may, by adding to the common name of any such product mere words of qualification or description, escape the regulation of the Administrator, then the fixing of a standard for commonly known foods becomes utterly futile as an instrument for the protection of the consuming public. Here is no arbitrary or fanciful name, neither "representative or misrepresentative" of a common food product, as in Judge Geiger's unreported case of *U. S. v. 247/8 Gallons of Smack* (E. D. Wis. 1926).<sup>3</sup> Such designations invite inquiry as to what the food really is. The present product is intended to satisfy the demand and supply the market for—catsup. Emphasis is laid on its conforming to standard except for the preservative. The argument defeats itself, for if it is an article of food, distinguished from the standard by the qualification, then other ingredients may be added or defined ingredients or processes omitted without conflicting with the regulation, if containers are truthfully labeled.

<sup>2</sup> The Canners' League of America, of which the appellant is a member, vainly sought an amendment to the standard for catsup. No standard was sought for catsup with preservative, nor was review had of the Administrator's

rejection of the amendment.

<sup>3</sup> Notice of judgment under Food and Drugs Act (1906) No. 14,416 (White and Gates, Decisions, p. 1181).



[*Quaker Oats Case*]

In *Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, it was said that the statutory purpose to fix a definition of identity of an article of food sold under its common or usual name, would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition, and so it was not an unreasonable choice of standards for the Administrator to adopt one which defined the familiar farina of commerce without permitting vitamin enrichment, and at the same time a standard for "enriched" farina which permitted a restoration of vitamins removed from whole wheat by milling. The respondent in that case had marketed "Quaker Farina Wheat Cereal, Enriched with Vitamin D". Since this did not conform either to the standard adopted for farina, or to the standard adopted for enriched farina, it was held to be misbranded, although the label there as truthfully described the product as does the present label. The district judge was unable to distinguish the present case from the *Quaker Oats* case, and neither can we.

In reviewing the text and legislative history of the present statute, Mr. Justice Stone, in the *Quaker Oats* case, pointed out that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had already been prohibited by the 1906 Act. The remedy chosen was not a requirement of informative labeling, rather, it was the purpose to authorize the Administrator to promulgate definitions and standards of identity under which the integrity of food products could be effectively maintained, and to require informative labeling only where no such standard had been promulgated; where the food did not purport to comply with the standard; or where the regulations permitted optional ingredients, or required their mention on the label, and that the provision for such standards of identity reflect a recognition by Congress of the inability of consumers to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other. The court was unable to say that such standard of identity, designed to eliminate a source of confusion to purchasers, will not promote honesty and fair dealing within the meaning of the statute.

[*Meaning of "Purport"*]

Neither the decision nor its rationalization in the *Quaker Oats* case, can be escaped by a product that looks, tastes, and smells like catsup, which caters to the market for catsup, which dealers bought, sold, ordered, and invoiced as catsup, without reference to the preservative, and which substituted for catsup on the tables of low priced restaurants. The observation in the opinion that it was the purpose of the Congress to require informative labeling, "where the food did not purport to comply with a standard" is not to be lifted out of its context, given a meaning repugnant to the decision, so as to limit "purport" to what is disclosed by the label and to that alone.

[*Appellant's Contentions Answered*]

The contention that Congress did not intend to, and may not prohibit shipment of non-deleterious substances, is fully answered both in the *Quaker Oats* case and *U. S. v. Carolene Products Co.*, 304 U. S. 144, where the regulation is in the interest of consumers. *Libby, McNeill & Libby v. U. S.*, 210 Fed. 148 (C. C. A. 4). While the recent case in the Sixth Circuit, *U. S. v. 2 Bags more or less of Poppy Seeds*,—Fed.—, decided January 31, 1945, involved a libel under the adulteration section of the Act, § 402(b) (3) and (4), it was there held that the appropriate inquiry is whether the ultimate purchaser will be misled. The contention of the appellant that transactions subsequent to the interstate movement of a food have no bearing upon whether the regulation or standard is avoided, and which is supported only by reference to the *Poppy Seed* case in the district court, 54 Fed. Supp. 706, now reversed, must be rejected. *Nolan v. Morgan*, 69 Fed. (2d) 471 (C. C. A. 7) and *U. S. v. Nesbitt Fruit Products Inc.*, 96 Fed. (2d) 972 (C. C. A. 5), did not involve standards of identity, and both cases were decided prior to the *Quaker Oats* case. The argument that an affirmance of the decision below will prevent the development of new foods and "lay a dead hand on progress" is one that may more appropriately be addressed to the Administrator or to Congress than to the courts.

[*Condemnation Affirmed*]

The order of condemnation is affirmed.



*U. S. v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint et al.*

**UNITED STATES v. 3 7/12 DOZEN PACKAGES, MORE OR LESS, OF NU-CHARME PERFECTED BROW TINT**

**UNITED STATES v. 26 CARTONS, MORE OR LESS, OF NU-CHARME PERFECTED BROW TINT**

United States District Court for the Western District of Louisiana,  
Shreveport Division. Nos. 1029 and 1105. Filed March 17,  
1945. 59 F. Supp. 284.

See 154 F. 2d 62, page 177. See also pages 159 and 161.

In providing for designated review of regulations in Section 701, Congress must have felt that this would afford an adequate remedy for determining the power, authority, and correctness of the Administrator's action.

Section 701 (e), Federal Food, Drug, and Cosmetic Act.

In a seizure suit against brow-tint, claimant asserted that the Administrator had acted without authority in issuing regulations which did not permit the use of a certain coal tar color in claimant's product, and that the regulations were unconstitutional because of want of proper notice and because they deprived claimant of property without due process of law. Except with respect to the Constitutional issue of due process, it did not appear that there was any other remedy "provided by law," pursuant to Section 701 (f)(6), by which the court could review the action of the Administrator complained of.

Sections 304 (a), 601 (a), 601 (e), 604, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Before the court could determine whether the notice and hearing held were sufficient to constitute due process, it would be necessary to have before it a certified copy of the proceedings had before the Administrator.

Sections 701 (e), 701 (g), Federal Food, Drug, and Cosmetic Act.

M. E. Lafargue and A. E. Bryson, Shreveport, La., for plaintiff.

H. V. Booth and C. B. Emery, Shreveport, La., and P. G. Alston, Texarkana, Ark., for defendant.

*[Nature of Cases]*

DAWKINS, J.: These two cases involve the same issues (and will be disposed of in one opinion) in which the Government seeks to condemn and have destroyed certain quantities of the product known as "NU-CHARME PERFECTED BROW TINT \* \* \*," found on analysis to consist essentially of para-phenylenediamine, approximately four per cent, dissolved in water \* \* \* and that the article is adulterated within the meaning of T. 21 USCA 361 (a), in that it contains a poisonous and deleterious substance, namely, paraphenylenediamine, which may render it injurious under the conditions prescribed in the labeling thereof, as follows:

"\* \* \* Use Glass, China or Wooden Dish for Mixing Fifteen (15) drops Solution No. 1 with Fifteen (15) drops Solution No. 2; to this add enough Powder No. 3 to make thick paste. Be sure paste will not run.

"Application

"Using small clean orange stick apply dye mixture to lashes . . . then to

brows. Leave mixture on until dry . . . 10 to 15 minutes.

\* \* \*

"Do not Let Patron Open Eyes Until All of Mixture Has been Removed.  
\* \* \*"

*[Proceedings in Cases]*

The seizure was made and appropriate proceedings taken for the condemnation as having been sold in interstate commerce. Thereupon, James B. Bird, doing business as Nu-Charme Laboratories, intervened and claimed ownership of the seized product. Among other things he admitted that it was a cosmetic within the intent and meaning of the Act of June 25th, 1938, known as the "Pure Food, Drug, and Cosmetic Act"; but denied that it was adulterated within the meaning of T. 21 USCA 361 (a) or that it contained poisonous and deleterious substances, which render it injurious to users under conditions of use prescribed in the label thereof. Claimant then quoted in detail the directions for preparation and use which he alleged accompanied the product.



On January 16, 1945, plaintiff filed an amended libel in which it was alleged as follows:

"that the article heretofore herein seized is further adulterated within the meaning of 21 U. S. C. 361 (e), in that it is not a hair dye and bears and contains a coal tar color that has not been listed for use in cosmetics in accordance with regulations of the Administrator of the Federal Security Agency pursuant to 21 U. S. C. 364, and is other than one from a batch that has been certified."

On February 19, 1945, the following proceedings were also filed: (1) a second amendment to the libel, from which the following is quoted:

"Notwithstanding, in order to have the pertinent regulations before the Court, libelant shows that the Federal Register of Tuesday, May 9, 1939, Volume 4, Number 89, beginning on page 1922, contains the following:

"Rules, Regulations, Orders

"Title 21—Food and Drugs

"Food and Drug Administration

"In the matter of public hearing for purpose of receiving evidence upon basis of which regulations may be promulgated for listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics: For certification of batches of such colors: For procedures thereunder: and for payment of fees therefor.

"Order of the secretary promulgating regulations effective on publication.

"Pursuant to, and under and by virtue of, the authority and direction of the Federal Food, Drug, and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U. S. C. 371 (e); Sec. 406 (b), 52 Stat. 1049; 21 U. S. C. 346 (b); Sec. 504, 52 Stat. 1052; 21 U. S. C. 354; Sec. 604, 52 Stat. 1055; 21 U. S. C. 364; Sec. 706, 52 Stat. 1058; 21 U. S. C. 376), and based upon substantial evidence of record at the hearing in the above-entitled matter, detailed findings of fact are made, as follows:

"Findings of Fact

"Coal-tar colors—Derivation—Scope of term.

"That coal-tar colors are materials consisting of one or more substances which either are made from coal-tar, or are capable of derivation from intermediates of the same identity as coal-tar intermediates. They include all substances from these sources which are themselves colored and impart their color to the substance to which they are applied, and they also include those compounds which do

not themselves possess the color imparted to the substance to which they are applied but which, when applied to such substance, impart color. (For example: Orange I is prepared from coal-tar intermediates. It is itself colored and imparts color when applied to a substance. Alizarin may be made either from coal-tar intermediates or from the root of the madder plant. It is colored and imparts color and is considered a coal-tar color whether derived from coal-tar or from a natural source. Paraphenylenediamine is colorless but is considered a coal-tar color, since it is derived from coal-tar and imparts color when applied to other substances.) Coal-tar colors may also include diluents or substrata. In the manufacture of coal-tar colors all impurities are not completely eliminated.

"2.

"Definitions of terms used in regulations. (Unnecessary here.)

\* \* \* \* \*

"3.

"No coal-tar color in the orbital area.

"That coal-tar colors are not harmless for use in preparations applied to the area of the eye, which means the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. No coal-tar color should be certified for use in a product to be applied to the area of the eye. A coal-tar color used in a product to be applied to this area should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use."

(2) a plea by the intervenor, attacking the constitutionality of Sec. 604 of the Act of June 25, 1938 (Ch. 675, 52 Stat. 1054, T. 21, 364, U. S. C. A.) if the court "should hold" that the Federal Security Administrator has the right and authority to promulgate regulations prohibiting the manufacture "of cosmetics containing coal tar color irrespective of the actual fact that such product is harmless when applied according to directions" as violating the 5th and 14th amendments to the Constitution of the United States; (3) a motion to dismiss the amended libels for reasons set forth at length in paragraphs (a) to (f) inclusive, which, stated in substance, are as follows: (a) The Act of Congress excludes from its provi-



*U. S. v. 37/12 Dozen Packages of Nu-Charme Perfected Brow Tint et al.*

sions eyelash dyes or eyebrow dyes; (b) alternatively, should the court hold that the administrator was given such authority by the Act, the amended bills "propose a new issue contradictory and inconsistent with the allegations of the original bill because the regulation \* \* \* provides the certification of any 'batches' containing coal tar \* \* \*"; (c) that the refusal of the administrator to certify any coal tar color, harmless or otherwise, is arbitrary and capricious, and confiscatory \* \* \*"; (d) said regulation "contravenes paragraph (a) of Sec. 361, 21 USCA in that it defines 'a poisonous or deleterious substance' to be other than the definition contained in paragraph a"; (e) that said regulations "set up a different standard of determining the use of cosmetics, particularly eyelash and eyebrow tints \* \* \* and redefines what is 'a poisonous and deleterious substance'"; and (f) that the administrator failed to give proper notice of hearing before prescribing such regulations as required by T. 21 Sec. 371 (e) USCA, and finally that intervenor had no notice of such hearing at all until the libels were filed.

On the same day, February 19th, intervenor filed answers to both amended libels.

Counsel for the Government, likewise on that day, filed what is styled "a motion for judgment on the pleadings" in which it was set forth that intervenor had answered the original libel admitting "the substantial allegations (of the libel) with exception that he denied the cosmetic contains a poisonous and deleterious substance, which may render it injurious to users under conditions prescribed on the label thereof"; that the Government then filed an amended libel, charging that the product "was not hair dye, but an eyelash and brow dye and it contained a coal tar color that has not been listed for use as a cosmetic \* \* \* pursuant to 21 U. S. C. A. 364, and is other than one from a batch that has been certified"; that the original answer admitted these allegations to the amended libel; and that the government filed a second amendment setting forth the rules and regulations as shown by the Federal Register "condemning a coal tar color to be used in a product to be applied in the area of the eye", which was likewise admitted by intervenor in his answer to said amendment, and this removes any dispute as to the facts, except as to the poisonous nature of the product, which was immaterial for the purpose of said motion for judgment. Counsel for in-

tervenor stated that if the court allowed the amendment and held that the administrator could legally refuse to certify any coal tar product for use in coloring of eyelashes and eyebrows, then there would be no question but that the government would be entitled to judgment. On the other hand, if it were concluded that the administrator did not have such authority or that intervenor had not been properly notified and given a chance to be heard at a hearing upon the matter before this ruling was made, then the matter should go to trial on the merits of whether the product, when used according to directions, was dangerous and injurious to the skin and eyes.

[Statutory Provisions for Review  
of Regulations]

When this Act of June 25, 1938, was under consideration by Congress, there was considerable discussion as to whether the powers to be exercised by the administrator should be subject to review by the courts, and the lawmakers went further in the matter of judicial review of his actions than has been provided in many other instances of delegation of power to make regulations having the effect of law. These provisions for review by the courts are found in Sec. 371 T. 21 U. S. C. A. Subsection (d) of section 371 provides:

"The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective \* \* \*, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder."

Subsection (e) dealing with hearing and making of regulations is as follows:

"The Administrator, on his own initiative or upon an application of any interested industry of substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this chapter: 341, 343 (j), 344 (a), 346 (a) and (b), 351 (b), 352 (d), 353 (h), 354 and 364. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 344 (a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be



heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on *substantial evidence of record* at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necessitating an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify therein to meet the emergency."

(Italics by the Writer.)

It will be noted that under subsection (e) the administrator may "on his own initiative or upon application of any interested *industry or substantial portion thereof* \* \* \* *shall* hold a public hearing upon a proposal to *issue, amend or repeal* any regulation contemplated by any of the following sections \* \* \* 364"; that he shall give appropriate notice, etc., and that no such order shall take effect until ninety days after its issue. The dates on which the orders or regulations were issued in this matter appeared in the quotation from the amended bill of the government above. But the portions so quoted, as appearing in the Federal Register of May 9, 1939, do not show how or when the notice of the hearing was given or on what date it was held. (This court does not have the 4th volume of the Federal Register, the latest number furnished it being Vol. 3, published in 1938.) However, subsection (g) provides that

"a certified copy of the transcript of the record of any proceedings under subsection (e) shall be furnished by the Administrator to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceedings arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f)."

This coupled with paragraph 6 of the last mentioned subsection (f) providing: "The remedies provided for in this section shall be in addition and not in substitution for any other remedies by law", would indicate that Congress had in mind that there might

arise in condemnation proceedings issues upon which proceedings before the administrator affecting the rights of the claimant under any particular libel would be such that the courts should consider and decide them, notwithstanding the remedies for review provided in subsection (f), permitting the going direct to the Circuit Court of Appeals having jurisdiction in the locality "where any person who may be adversely affected by such order resides \* \* \* or has his place of business" instead of resorting to an original action in a court of first instance, such as the United States District Courts. In *Security Adm. v. Quaker Oats Co.*, 318 U. S. 218, on p. 227, the Supreme Court, with Chief Justice Stone as its organ, in referring to the procedure provided in subsection (f), states:

"The review provisions were patterned after those by which Congress has provided for the review of 'quasi judicial' orders of the Federal Trade Commission and other agencies, which we have many times had occasion to construe. Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body."

#### [Grounds of Attack upon Regulations]

It becomes necessary therefore, for this court to analyze the grounds of attack upon the regulations. This is particularly true since it has, after hearing, allowed the amended libel, which, in effect, says that claimant's product was not made in compliance with the regulations, because the administrator had ruled that any and all preparations intended for use as eyelash or brow dyes containing coal tar are dangerous and therefore refused to certify any batches as harmless. Claimant admits that the administrator has excluded the use of coal tar coloring from such dyes.

Taking up these contentions, we find that they fall into two classes, thus: (1) those in which it is claimed the administrator acted beyond or without authority under the statute; and (2) the alleged unconstitutionality based upon want of proper notice and the action of the administrator in denying the right to use coal tar in claimant's preparation, which amounts to taking of his property without due process of law. As pointed out earlier herein, those in the first class are raised principally in the motion to dismiss the amended libels, while in the plea of unconstitutionality it is substantially alleged that if the court should



*U. S. v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint et al.*

hold that the administrator, under the Act, has the right and authority to promulgate regulations prohibiting the use of cosmetics containing coal tar color, irrespective of the actual fact that such product is harmless when applied according to directions, then the statute is unconstitutional and conflicts with the 5th and 14th amendments; and further, "in the alternative", that section 371 T. 21 U. S. C. A. violates the 14th amendment in that it fails to provide "effective notice to those who may be vitally concerned by such contemplated orders, regulations, etc."

*[Congress Felt Review Afforded Adequate Remedy]*

I think it must be conceded that Congress, in providing for review of orders and regulations made by the administrator, in the manner and by the particular procedure and courts specified in subsection (f) of 371, must have felt that this would afford adequate remedy for determining the power, authority and correctness of the administrator's action within the statute; and that to provide stability, a reasonable limit, in the matter of time, should be fixed for those contests, which it set at ninety days. (This is not to say that the issue of sufficient notice, such as to provide due process, could not be raised also in such proceedings and reviewed in what the Supreme Court in *Security Adm. v. Quaker Oats, supra*, termed "respondent's appeal from this order" to the Court of Appeals.)

*[No Other Remedy Provided]*

Besides, in the first sentence of subsection (e) of Sec. 371, the "Administrator on his own initiative or on the application of any interested industry or substantial portion thereof, shall hold a public hearing upon a proposal" not only "to issue" but to "amend or repeal" any regulation contemplated by "any section of the act," including Section 364 of T. 21 U. S. C. A., requiring that he "shall promulgate regulations providing for the listing of coal tar colors, which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless dilutents". In other words, regardless of the nature of the regulation and of the fact that it might have been adopted with full compliance as to notice, hearing, review,

etc., it would seem "that any industry or substantial portion thereof" could make application "to amend or repeal" the same. Of course, what should constitute an "industry or substantial portion thereof" is somewhat indefinite and uncertain, but the act itself does seem to provide a means for raising these issues, first before the administrator, and then, by direct appeal to the court of appeals, thus insuring a more speedy determination than if submitted to the courts of original jurisdiction, such as the present proceeding. Hence, except as to the constitutional issues of due process under the 5th and 14th amendments, raised by the charge of insufficient provision for notice and opportunity to this claimant to be heard before adoption of the regulations quoted above from the second amended bill and the wrongful taking of his property, it does not appear to this court that there is any other remedy "provided by law," and none has been cited or referred to by complainant, by which this court can review the action of the administrator complained of in either the motion to dismiss or otherwise, which existed prior to the enactment of subsection 371 (f), and as to which the latter would be "in addition."

*[Copy of Proceedings Essential To Determine Due Process]*

Before this court can determine whether the notice and hearing held were sufficient to constitute due process, it will be necessary to have before it a certified copy of the proceedings had before the administrator, as provided by subsection (e) of Sec. 371, which can be obtained by claimant for use herein, under subsection (g).

*[Motion To Dismiss Denied; Constitutional Issues Held Open]*

The motion to dismiss will therefore be denied, but the matter is held open upon the issues of the constitutional questions to afford the parties an opportunity to obtain and file in this case certified copies of the proceedings had before the administrator, showing specifically the time and manner of giving notice to the claimant and others in said industry, as well as the character of the hearing.

Thus done and signed in Chambers at Monroe, Louisiana, on this March 16, 1945.



## UNITED STATES v. 26 DOZEN BOTTLES, MORE OR LESS, OF "WHEATAMIN BRAND CEVIGARDS"

United States District Court for the Western District of Michigan, Southern Division. No. 1600 Admiralty. March 23, 1945. 60 F. Supp. 626.

The words "district of reasonable proximity to the claimant's principal place of business," as used in the seizure section, do not include authority to remove a seizure action to the district within which the claimant's principal place of business is located.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Joseph F. Deeb, U. S. Attorney, Grand Rapids, Mich., for plaintiff.

Warner, Norcross & Judd, Grand Rapids, Mich.; Gossett, Ellis, Dietrich & Tyler, Kansas City, Mo.; for defendants.

### **In re: Motion to Remand**

*[Interpretation of "Reasonable Proximity"]*

RAYMOND, District Judge: Application of the principles of statutory construction discussed by Judge McAllister in the case of *Commissioner of Internal Revenue v. Strong Mfg. Co.*, 6 Cir., 124 F. (2d) 360, 364, results in the conclusion that the words "district of reasonable proximity to the claimant's principal place of business" as used in Section 334 (a) of Title 21 U. S. C., providing for removal for trial to another district of a libel for condemnation proceedings under the Federal Food, Drug, and Cosmetic Act, do not include authority

to remove to the district within which claimant's principal place of business is located. (See *U. S. v. Six Dozen Bottles, etc.*, 55 F. Supp. 458; *U. S. v. 168 Dozen, etc. Bromo Seltzer*, (unreported) decided May 25, 1939, by Judge Clancy, S. District of New York; *U. S. v. 74 Cases, etc.*, 55 F. Supp. 745.)

*[Order To Be Entered Remanding Cause]*

An order will accordingly be entered remanding said cause to the United States District Court for the Western District of Missouri, Western Division.

## UNITED STATES v. 600 UNITS, MORE OR LESS, EACH CONTAINING 3 BOTTLES OF "NUE-OVO" AND STOCKS OF CIRCULARS ENTITLED "INFORMATION ON NUE-OVO AND ITS VALUE IN ARTHRITIC AND OTHER RHEUMATOID SYMPTOMS"

United States District Court for the Western District of Missouri, Western Division. No. 2148. Decided March 23, 1945. Filed March 24, 1945.  
 60 F. Supp. 144.

A "district of reasonable proximity to the claimant's principal place of business," in Section 304 (a), means a district other than that of the domicile of the claimant.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

An order of removal, transferring a seizure action to a district wherein claimant's principal place of business was located, was amended to remove the case to a contiguous district.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Maurice M. Milligan, for plaintiff.

Frank H. Terrell, Kansas City, Mo., for defendant.



### Memorandum Opinion on Motion To Vacate Order of Transfer

#### [*Order of Transfer*]

ALBERT L. REEVES, U. S. District Judge: On the first day of March 1945 this court entered an order removing and transferring the above-entitled cause to the district court of the United States sitting at Portland, Oregon, for trial. This is the place intervenor's business is located. The order was made pursuant to motion filed by the intervenor for removal and transfer of the libel proceeding pursuant to provisions of Section 334 (a), Title 21 U. S. C. A. The language of the motion conforms to the statutory requirements, as follows:

"In any case where the number of libel for condemnation proceedings is limited \* \* \* the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

#### [*Varying Interpretations of Statute*]

At the time the order was made the United States Attorney appeared with counsel for the intervenor or claimant and then insisted that the only order that could be properly made was one transferring and removing the case to the Western District of Washington, being a district of reasonable proximity to the claimant's principal place of business. The court was then of the opinion that the statute contemplated a place for holding court as near to the principal place of business of the claimant as practicable. Such a place of holding court was at Portland, Oregon. A hurried interpretation of the statute seemed to warrant the court in removing the case for trial to that point. The District Attorney did not agree to the order and, as indicated, has subsequently filed a motion to vacate the order of removal. The parties have favored the court with briefs and suggestions in support of their respective contentions. Congressional records showing the history of the legislation indicate that the Senate

attempted to provide that a case of this kind might be removed and transferred to the district court in which claimant's principal place of business was located, while, on the other hand, the House of Representatives attempted to provide that the removal could be made only to a district court of a state contiguous to the state of claimant's principal place of business. Both the Senate and House receded from their several extreme positions. The Senate no longer contended that the transfer should be made to a state contiguous to that of the claimant's domicile. The compromise involved the use of the words "a district of reasonable proximity to the claimant's principal place of business." In order to give a proper meaning to the statute, in view of the concessions made by the two legislative bodies, a district of reasonable proximity would mean a district other than that of the domicile of the claimant, whether in the same state or a contiguous state. Oregon has but one district, whereas the State of Washington has two districts. The Western District of Washington, Southern Division, is a district of "reasonable proximity to the claimant's principal place of business."

#### [*Case Not of First Impression*]

1. A statement of the facts and the law, as above, suggests a proper interpretation of the statute and what order should be made in the case. This is not a case of first impression.

#### [*Dr. Peter's Kuriko Case*]

In the case of *United States v. 6 dozen bottles, etc.*, 55 Fed. Supp. 458, Judge Duffy of the District Court of the Eastern District of Wisconsin, was presiding in a similar case. That case, however, had been transferred to his district from one of the district courts in the State of Washington. The claimant in that case had originally applied to one of the district judges in one of the districts of Washington to transfer the case to the Northern District of Illinois for the reason that the claimant's principal place of business was in Chicago. The District Judge declined to transfer the case to the Northern District of Illinois but did order its removal or transfer to the Eastern District of Wisconsin, being a district of reasonable proximity to the claimant's place of business. After the transfer to that district of reasonable proximity the claimant renewed its motion for a transfer to the



Northern District of Illinois. While District Judge Duffy ruled that the claimant had exhausted his right of removal as having been accorded by statute but one removal, nevertheless he took occasion to say:

"Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, *because the same would not have been and is not authorized. In the absence of stipulation between the parties, the power of removal of the court of original jurisdiction is limited and restricted.* Such court is required to order removal to 'a district of reasonable proximity to the claimant's principal place of business.' Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois."

[*Claimant's Request for Transfer*]

2. Moreover, in this case, the claimant apparently so interpreted the statute for the reason that, in its motion to transfer it said:

"Intervenor further states that the United States District Court next closest

to Intervenor's place of business is the District Court of the United States for the District of Washington, Western District, Southern Division, sitting at Tacoma, Washington, which said district court is approximately 150 miles from Portland, Oregon.

"Wherefore, Intervenor prays that said cause be transferred and removed from this Court to a district of reasonable proximity to Intervenor's principal place of business."

It will be observed that the intervenor does not ask that the case be transferred to the district in which the claimant's principal place of business is located.

[*Order of Removal Amended*]

In view of the above, the order of removal transferring the case for trial to the District Court of Oregon, sitting at Portland should be amended so that the order of removal will be to the Western District of Washington, Southern Division, at Tacoma, Washington, and it will be so ordered.

---

**UNITED STATES v. 24 CANS CONTAINING A TOTAL  
OF APPROXIMATELY 1833 POUNDS OF LADLED  
BUTTER IN POSSESSION OF CLOVERLEAF  
BUTTER CO., BIRMINGHAM, ALABAMA,  
ET AL.**

United States Circuit Court of Appeals for the Fifth Circuit. No. 11040.

March 27, 1945. 148 F. 2d 365.

Certiorari denied, 326 U. S. 752 (1945).

The Renovated Butter Act has not pre-empted the field as opposed to federal action, under the Federal Food, Drug, and Cosmetic Act, against packing stock butter which is to be renovated.

Section 201 (f), Federal Food, Drug, and Cosmetic Act.

It was not intended by Congress, in the Renovated Butter Act, to leave packing stock butter manufacturers completely free to use, in making their completed product, any kind of filthy material in the hope that it would be removed.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

If Congress had intended to take packing stock butter out of the Federal Food, Drug, and Cosmetic Act it could easily have done so. Implied repeal or limitation, however, of one act by another is never favored. Only where it is found that it is not possible for two statutes to co-exist can an act be held to repeal or limit another, and then only in respect to the precise point of conflict.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

In a seizure action against packing stock butter, it was held that there is no fatal inconsistency between the Renovated Butter Act and the Federal Food, Drug, and Cosmetic Act.

Sections 201 (f), 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.



Jim C. Smith, U. S. Attorney, for appellant.

Erle Pettus, Sr., Horace C. Wilkinson, and Victor H. Smith, all of Birmingham, Ala., for appellees.

Before HUTCHESON, HOLMES, and McCORD, Circuit Judges.

[Contention of United States]

HUTCHESON, Circuit Judge: Cloverleaf Butter Company is an operator in Birmingham, Alabama, under federal license, of a renovated butter factory.<sup>1</sup> Claiming that packing stock butter consigned to Cloverleaf was adulterated in that it consisted in whole or in part of a filthy or decomposed animal substance, the United States brought libels of condemnation under the Federal Food, Drug, and Cosmetic Act of 1938.<sup>2</sup> Urging successfully below against condemnation under the Federal Food and Drug Act what it had urged successfully in its injunction suit against the state authorities, that the handling and use of packing stock butter was governed exclusively by the Renovated Butter Act and the regulations promulgated by the Secretary of Agriculture thereunder, and that the materials which it used in its factory were not subject to seizure, claimant obtained an order dismissing the libels. Appealing from the order, the United States, in support of its position that the Food and Drug Act does apply and the seized products may be libeled under it, points to the admitted fact that the seized stock is used as a component of renovated butter, to the language of the Act which authorizes the seizure of any food which is adulterated, and to Section 321 (f), Title 21, which defines food to mean "articles used for food or drink for man or other animals \* \* \* and (3) articles used for components of any such articles". It points, too, to the opinion of this court in *In re: United States*, 140 Fed. (2) 19, directing the district court to proceed under the libels to determine whether the seized product "is really food under the Act and is really adulterated as alleged" and to enter its decree accordingly. Finally, it points to the holding of the majority in *Cloverleaf v. Patterson*, 315 U. S. 148:

"Further, we agree with respondent's contention that there is no authority to confiscate or destroy materials under the renovated butter act. It should be noted

that packing stock adulterated under the definitions of Sec. 402 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1046, when introduced into or while in interstate commerce may be confiscated under Sec. 304 while in interstate commerce or at any time thereafter. Cf. *United States v. Nine Barrels of Butter*, 241, F. 499." p. 163.

"\* \* \* Confiscation by the state of material in production nullifies federal discretion over ingredients." p. 168.

"\* \* \* To uphold the power of the State of Alabama to condemn the material in the factory, while it was under federal observation and while federal enforcement deemed it wholesome, would not only hamper the administration of the federal act but would be inconsistent with its requirements. Whether the sanction used to enforce the regulation is condemnation of the material or the product is not significant. Since there was federal regulation of the materials and composition of the manufactured article, there could not be similar state regulation of the same subject." p. 169.

[Contention of Claimant]

Cloverleaf, on its part, points to the provision of the Renovated Butter Act, to the history of the renovated butter industry, and to the holding of the Supreme Court in the *Cloverleaf* case; that the act assumes, and, in view of the character of the industry must assume, that all packing stock from which renovated butter is made is more or less adulterated, and, therefore, the scheme of the act is to subject the finished product, rather than its ingredients, to the inspection and scrutiny of the Department of Agriculture. So pointing, it insists that if the Food and Drug Act is held to apply, renovated butter cannot be made, and that there is, therefore, such an inconsistency between the two statutes as that as to ingredients of renovated butter, the Renovated Butter Act supersedes and excludes the Food and Drug Act and its administrators. Relying heavily on the opinion of the majority of

<sup>1</sup> See *Cloverleaf Co. v. Patterson*, 315 U. S. 148, an injunction suit against condemnation by state authorities of packing stock butter, in which claimant's activities are fully set out and

it was held by a divided court that the Renovated Butter Act of 1902, as amended USCA, Title 26, Secs. 2320 to 2327 excluded state action.

<sup>2</sup> Title 21 USCA, Sec. 342(a)(3); Sec. 402(a)(3).



the Supreme Court in the *Cloverleaf* case, that Congress had, in the Renovated Butter Act, assumed for the Department of Agriculture such complete control over the field as to oust state inspection and state supervision of ingredients, Cloverleaf insists that the same reasoning which supported the decision in its favor there compels one in its favor here, leaving it as to the components of its finished product completely immune from their seizure and condemnation.

*[No Inconsistency Between Renovated Butter Act and Food and Drug Act]*

We cannot at all agree. We accept, as we must until it is reversed, the view of the majority, that as between state and federal power, an act which does not give the Department of Agriculture the right to inspect and condemn filthy ingredients of renovated butter, has yet pre-empted the field as against state inspection and condemnation of such filthy substances. Nothing, however, in the opinion lends support to the view which the exigencies of its situation require Cloverleaf now to advance, that the Renovated Butter Act has pre-empted the field for the Department of Agriculture not only as against state action but as against federal action as well. The authoritative statement of the majority opinion that though the Renovated Butter Act made no provision for the seizure by the Department of Agriculture of butter stock, inspection and seizure of filthy and otherwise adulterated stock could be had under the Food and Drug Act, and, therefore, it could not be successfully claimed that filthy packing stock was immune from seizure, completely destroys appellee's position that the one federal act is exclusive of the other. Indeed, unless the statement in one of the dissenting opinions in that case that "The result of the decision is to deny Alabama the power to protect the health of its citizens without replacing such protection by that of the Federal Government" is to be accepted, despite the disclaimer of the majority, it must be held that it was certainly not intended by Congress to leave packing stock butter manufacturers completely free to use in making their completed product any kind of filthy and putrid material they chose to use in the faith, the substance of things hoped for, the evidence of things not seen, that, in homely phrase, it will all come out in the wash. When the Food and Drug Act is considered in the light of its purpose to protect the public from adulterated and unfit materials, it

would take the strongest kind of showing that its protective provisions had been limited not directly but by implication, and Cloverleaf, in maintaining that position here has a heavier burden than it can bear. It does, indeed, show that the renovating process is well adapted to remove all impurities, that renovated butter is good butter, that all packing stock has to be renovated, that all of it comes into the plant more or less adulterated with extraneous and deleterious substances in it, or otherwise unfit in its then condition for human food, and that if all packing stock were to be condemned because not fit for human food, no matter how slight the adulteration, the renovated butter industry could not survive. But these considerations are for Congress, and if Congress had intended to take packing stock butter out of the Food and Drug Act, it could very easily have done so either by amending the statutory definition of food to exclude materials that go into the finished product or by expressly excluding from the Act ingredients of renovated butter. Implied repeal or limitation of one act by another is never favored. It is not for the courts, unless the conflict between two acts is inescapable and compelling, to exclude from the coverage of an act matters which its terms expressly include, on the theory that another act, whose general purpose seems inconsistent has impliedly repealed or limited the act under review. Only where it is found that it is not possible for both acts to co-exist can an act be held to repeal or limit another, and then only in respect to the precise point of conflict. It certainly cannot be said that there is any fatal inconsistency between the two acts here. If Congress wanted to encourage the making of packing stock butter out of any materials that the manufacturers can get hold of in reliance on their claims that no matter how filthy the ingredients, the finished products will be pure, or the impurity can be, or will be, detected, it could, of course, take packing stock butter out of the Food and Drug Act. We find no support in the Acts for a finding of a repealer by implication, indeed, we think it plain that there is no necessary inconsistency between them. What was intended by the Renovated Butter Act, and all that was intended, was that renovated butter could be made out of stock which, while not in its then state fit for human consumption, was yet not so unfit as to require its condemnation. It was not intended that renovated butter be made out



*U. S. v. 37/12 Dozen Packages of Nu-Charme Perfected Brow Tint*

of any kind of stock, no matter how filthy or putrid, in the pious hope that its filthiness and putrescence would, in the process of renovating, be purged away. Thus Congress, while authorizing the making of renovated butter, left to proper administration the supervision of the ingredients, authorizing their seizure and condemnation

whenever they were of such character as to be deemed deleterious or otherwise unfit for use. The libels were wrongfully dismissed. The judgments dismissing them are reversed and the causes are remanded with directions to proceed with the libels, in accordance with our former opinion in 140 F. (2) 19, and herewith.

**UNITED STATES v. 3 7/12 DOZEN PACKAGES, MORE  
OR LESS, OF NU-CHARME PERFECTED  
BROW TINT**

**UNITED STATES v. 26 CARTONS OF NU-CHARME  
PERFECTED BROW TINT**

United States District Court for the Western District of Louisiana, Shreveport Division. Civil Actions Nos. 1029 and 1105. Filed August 7, 1945. 61 F. Supp. 847.

See 154 F. 2d 62, page 177.

See also pages 149 and 161.

In a seizure action against brow tint, claimant contended that there had been a violation of due process because of lack of notice and adequate hearing leading to the promulgation of the regulation. It was shown that all the notice possible had been given, in view of the large numbers of persons and industries involved; that all those who had filed appearances were given ten days in which to file briefs or arguments; and that such exceptions as had been filed were duly considered by the Administrator. Consequently, due process had been had and claimant's plea of unconstitutionality was not well-taken.

Sections 304 (a), 601 (a), 601 (e), 604, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

M. E. Lafargue, U. S. Attorney, and A. E. Bryson, Shreveport, La., for plaintiff.

H. V. Booth & C. B. Emery, Shreveport, and P. G. Alston, Texarkana, Ark., for defendant.

*[Previous Opinion]*

DAWKINS, District Judge: In the opinion handed down in these consolidated cases on March 16, 1945, it was said:

"The motion to dismiss will therefore be denied, but the matter is held open upon the issues of the constitutional questions to afford an opportunity to obtain and file in this case certified copies of the proceedings had before the administrator, showing specifically the time and manner of giving notice to the claimant and others in said industry, as well as the character of the hearing."

*[Constitutional Issue Involved]*

This ruling was made upon motion of the claimant or intervenor to dismiss the libel, and as indicated therein, the Court considered the only serious issue to be the constitutional one as to whether a reasonable opportunity to be heard had been afforded the intervenor and others in its position be-

fore the regulation prohibiting the use of coal-tar in the manufacture of eye-lash and brow tints was adopted.

*[Material Filed in Record Listed]*

In compliance with the suggestion or requirement contained in the concluding paragraph of the opinion quoted above, counsel for the government obtained and filed in the record the following:

(1) A press release under date of January 6, 1939, of a hearing to be had on February 6, 1939, in one of the buildings occupied by the Secretary of Agriculture in Washington, D. C., at which all persons using or proposing to use coal-tar or its products in the manufacture of commodities for sale to the public, would be given an opportunity to be heard, either in person or through representative;

(2) Three copies of the Federal Register of dates January 7, April 8 and 9, respectively.



(1) The press release stated that at the proposed hearing there would be considered "some one hundred and thirty-two coal tar colors on which interested persons may submit testimony concerning harmlessness and suitability for use." It also stated that, "It is not proposed to certify any color for use in eyelash or eyebrow dyes." Presumably this release was published in the various trade journals of the many businesses or industries using coal-tar colors.

(2) The Federal Register of January 7, 1939, among other things dealing with coal-tar colors, etc., contained the following:

"Notice of public hearings for the purpose of receiving evidence upon the basis of which regulations may be promulgated providing for the listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics; for the certification of batches of such colors; for procedures thereunder; and for the payment of fees therefor."

\* \* \* \* \*

"(o) The authorization contained in these regulations for the certification of coal-tar colors for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, shall not be considered to authorize the certification of any coal-tar color for use in an eyelash dye or any eyebrow dye. A coal-tar color so used shall be considered to be from a batch that has not been certified in accordance with these regulations, even though such color is from a batch that has been certified for other use."

The issue of April 8, 1939 contained the following:

"Department of Agriculture.

"Food and Drug Administration.

"In the matter of public hearing for purpose of receiving evidence upon basis of which regulations may be promulgated providing for listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics, drugs and cosmetics, and externally applied drugs and cosmetics; for certification of batches of such colors; for procedures thereunder; and for payment of fees therefor."

\* \* \* \* \*

"No direct, positive testimony was introduced by other interested persons to controvert, or tending to controvert, the testimony introduced by the Department to the effect that the application of any coal-tar color to the orbital area is liable to cause serious consequences, even re-

sulting in impairment or loss of sight, and that no coal-tar color should be considered for listing for use in that area."

\* \* \* \* \*

"No coal-tar color in the orbital area. That coal-tar colors are not harmless for use in preparations applied to the eye. The anatomical structure of the eye includes the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. A coal-tar color which is certified for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, should not be certified for use in a product to be applied to the eye. A coal-tar color used in a product to be applied to the eye should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use. (R., pp. 32, 33, 78, 234-37, 413, 437, 438, 498, 599, 433; Government's Exhibit No. 1.)"

The issue of May 9, 1939, contained the following, among others, on the subject of use of coal tar for colors:

"Rules, Regulations, Orders

"Title 21—Food and Drugs

"Food and Drug Administration

"In the matter of public hearing for purpose of receiving evidence upon basis of which regulations may be promulgated for listing of coal-tar colors which are harmless and suitable for use in foods, drugs and cosmetics, and externally applied drugs and cosmetics; for certification of batches of such colors; for procedures thereunder; and for payment of fees therefor

"Order of the secretary promulgating regulations effective on publication.

"Pursuant to, and under and by virtue of, the authority and direction of the Federal Food, Drugs, and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U. S. C. 371 (e); Sec. 406 (b), 52 Stat. 1049; 21 U. S. C. 346 (b); Sec. 504, 52 Stat. 1052; 21 U. S. C. 354; Sec. 706, 52 Stat. 1058; 21 U. S. C. 376), and based upon substantial evidence of record at the hearing in the above entitled matter, detailed findings of fact are made, as follows:

\* \* \* \* \*

"No coal-tar color in the orbital area. That coal-tar colors are not harmless for use in preparations applied to the area of the eye, which means the area



*U. S. v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint*

bounded by the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. No coal-tar color should be certified for use in a product to be applied to the area of the eye. A coal-tar color used in a product to be applied to this area should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use."

*[Opportunity for Hearing]*

From this showing it is evident that the claimant and all other interested persons were given all the notice possible, in view of the very large numbers of persons and industries involved. It further appears that all of those who filed appearances either in "person or through representative", were given ten days in which to file briefs or arguments upon any point involved; and that such exceptions as were filed were duly

considered, some sustained and others rejected. None appeared to have been made to the regulation providing that no batches of dye would be certified for use in eyelash or eyebrow tint.

On April 19, 1945, a further hearing was had by the court in this case, at which these exhibits were filed. Subsequently, in the month of July, the exact date does not appear in the minutes, counsel for claimant brought the matter to the attention of the court, and advised that he did not intend to file further briefs, as had been suggested at the time of the hearing, and requested that the case be disposed of as it stood.

*[Existence of Due Process]*

Without finding it necessary to go further into the facts or law thus presented, it is sufficient to say that, in my opinion, there was due process and a compliance with the statute and that the plea of unconstitutionality of intervenor must fail.

*[Motion to Dismiss Overruled]*

The motion to dismiss will therefore be overruled.

**UNITED STATES v. 3 7/12 DOZEN PACKAGES, MORE  
OR LESS, OF NU-CHARME PERFECTED  
BROW TINT**

**UNITED STATES v. 26 CARTONS OF NU-CHARME  
PERFECTED BROW TINT**

United States District Court for the Western District of Louisiana, Shreveport Division. Civil Actions Nos. 1029 and 1105. Filed August 22, 1945. 61 F. Supp. 850.

Affirmed, 154 F. 2d 62. See page 177.

See also pages 149 and 159.

The only question that could be raised in a seizure action, concerning regulations which prevented the use of coal-tar in the claimant's product, was the one of compliance with the due-process clause of the Constitution.

Sections 304 (a), 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

The claimant admitted that his product was made from coal-tar not properly certified, in violation of regulations issued by the Administrator. Notwithstanding the claimant's denial that his product was dangerous, his admission was sufficient to warrant sustaining the seizure, and the action of the Administrator on the evidence produced at the hearing could be reviewed only through the appellate procedure provided by the Act.

Sections 601 (a), 601 (e), 604, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

M. E. Lafargue, U. S. Atty., and A. E. Bryson, Shreveport, La., for plaintiff.

H. V. Booth and C. B. Emery, Shreveport, La., and P. G. Alston, Texarkana, Ark., for defendant.



[*Previous Court Proceedings*]

DAWKINS, District Judge: The nature of this case, including pleadings and issues, was fully set forth in the opinions handed down by this court on March 17 and August 5th, 1945, and will not be repeated.

[*Sole Question To Be Considered*]

It was held that the only question that could be considered was the one of compliance with the due process clause of the Federal Constitution, by the Administrator, in adopting the regulations which prevent the use of coal-tar or its derivatives in the manufacture of eyelash or eyebrow coloring. It was held that, if sufficient notice and opportunity to be heard, within Constitutional requirements, had been afforded to the claimant here, and others in a similar situation, that the sole procedure for a review of the action of the Administrator is provided by the statute itself, and that is, through appeal from the ruling of the Administrator to the Circuit Court of Appeals having jurisdiction.

See sub-paragraph (f) Sec. 371 T. 21 U. S. C. A.

[*Defendant's Admission Sufficient To Grant Injunction*]

The bill in this case, as amended, charges that the product in question is made from coal-tar or a coal-tar derivative, which has not been certified for use therein, in violation of the regulations adopted by the Administrator. This is admitted by defendant, but he denies that his product is dangerous when applied according to directions. In this situation I am of the opinion that the admission is sufficient to warrant granting of the injunction and that the action of the Administrator on the evidence produced at the hearing can be reviewed only through the appellate procedure provided by the Act.

[*Summary Judgment*]

There should be summary judgment as prayed for.

---

**UNITED STATES v. 254 CASES AND 499 CASES, EACH  
 CONTAINING 48 CANS, OF AN ARTICLE LABELED  
 IN PART, "NET CONTENTS 10 OZ. AVOIR. BABY  
 BRAND TOMATO SAUCE"; UDDO &  
 TAORMINA COMPANY,  
 CLAIMANT**

United States District Court, Eastern District of Arkansas, Eastern Division.  
 Civil Action No. H-214. December 21, 1945. 63 F. Supp. 916.

Where a charge of adulteration was ignored throughout the trial of a seizure action, and was not referred to in oral argument or mentioned in the briefs, the court would assume that it had been abandoned.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

In a seizure action against product labeled as "tomato sauce," evidence revealed that dealers in, and consumers of, tomato products generally throughout the United States consider tomato sauce to be a spiced product containing not less than 8.37 per cent of salt-free tomato solids. The seized article failed to meet the requirements of tomato sauce in that it was not spiced and contained but 6.5 per cent of salt-free tomato solids.

Sections 304 (a), 403 (a), 403 (b), Federal Food, Drug, and Cosmetic Act.

The product was held to be misbranded notwithstanding the fact that in four states the claimant's product had been accepted by the consuming public as tomato sauce for a long period of time, since the question was what do buyers throughout the United States understand tomato sauce to be.

Sections 304 (a), 403 (a), Federal Food, Drug, and Cosmetic Act.

The seized product should be condemned since it was misbranded, but, being a wholesome food, should not be destroyed.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.



*U. S. v. 254 Cases et al. "Baby Brand Tomato Sauce"*

Sam Rorex, U. S. Attorney, and W. H. Gregory, Assistant U. S. Attorney, both of Little Rock, Ark., for libelant.

Buzbee, Harrison & Wright, and Edward L. Wright, of Little Rock, Ark., for claimant, Uddo & Taormina.

*[Nature of Proceeding]*

HARRY J. LEMLEY, District Judge: This case arises under the Federal Food, Drug, and Cosmetic Act of June 25, 1938, and more particularly under those provisions of the Act prohibiting the introduction, or delivery for, introduction into interstate commerce of any food that is adulterated or misbranded, and for seizure thereof. 21 U. S. C. A. Secs. 331, 334, 342 and 343.

*[Information Filed To Condemn Tomato Sauce]*

The United States filed an information herein for the condemnation of two lots of 254 and 499 cases, respectively, containing 48 ten ounce cans each of a product labeled; in part, "Baby Brand Tomato Sauce," and seized the same pending this litigation.

*[Allegations]*

It was alleged in the information that the cases in question were in the possession of the Interstate Grocer Company, of Helena, Arkansas, having been shipped to said company in interstate commerce from Crystal Springs, Mississippi, by Uddo & Taormina Company, of that point.

The information further alleged that the article was adulterated in violation of Sec. 342 (b) (2), Title 21, U. S. C. A., in that an unconcentrated or a slightly concentrated unspiced tomato liquid with added salt had been substituted for tomato sauce, "an article understood to be a spiced comminuted tomato product which is more concentrated than this article."

It was further alleged that the product was misbranded in violation of Sec. 343 (a), Title 21, U. S. C. A., "in that the label statement 'Tomato Sauce' is false and misleading as applied to an unconcentrated or slightly concentrated comminuted tomato liquid with added salt."

*[Misbranding Tomato Sauce Denied]*

The Uddo & Taormina Company intervened and filed an answer herein claiming ownership of the goods, and denying that the seized article was adulterated or misbranded in violation of the statute.

*[Case Tried by Court]*

The case was tried to the Court and has been submitted on oral argument and written briefs.

*[Adulteration Charge Disregarded]*

The charge of adulteration was ignored throughout the trial, and was not referred to in oral argument or mentioned in the briefs; so we take it that it has been abandoned.

*[Part of Act Quoted]*

The Act prohibiting the introduction into interstate commerce of any food which has been misbranded provides, in part, that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular."

*[Government's Contentions]*

It is the contention of the Government that the seized product is misbranded "Tomato Sauce" in that it is not tomato sauce, but something entirely different. The Government contends that tomato sauce is a spiced concentrated tomato product, containing at least 8.37% of salt-free tomato solids, whereas the article under consideration is unspiced and contains only 6.5% of salt-free tomato solids. It is conceded that no regulation has been promulgated by the Administrator, establishing and fixing any definition and standard of identity, or quality, for tomato sauce, as authorized by law, but it is contended that tomato sauce is generally understood by the trade and consuming public throughout the country to be a spiced, concentrated tomato product, containing at least 8.37% of salt-free tomato solids, and that the public would be misled and deceived by the brand of "Tomato Sauce" on an unspiced product containing less than that per cent of such solids.

*[Claimant's Contention]*

The claimant bases its contention that the goods are not misbranded on the proposition that it was a pioneer in the manufacture of tomato sauce in America, having canned the product under consideration and labeled it as tomato sauce for more than



thirty years, during all of which period it was sold and distributed in the trade territory of Louisiana, Mississippi, Arkansas, and Western Tennessee, and there accepted as tomato sauce.

*[Stipulation by Parties]*

It was stipulated by the parties that the goods moved in interstate commerce as was alleged in the information.

*[History of Product]*

The product under consideration is processed by the claimant, Uddo & Taormina Company, at Crystal Springs, Copiah County, Mississippi. Copiah County is in an old tomato raising section. The founder of the company, Mr. R. Raspanti, who testified in the case and whose testimony is hereinafter referred to in detail, came to Crystal Springs in 1914 and established a cannery, which has been in operation ever since.

*[Processing Method]*

The tomatoes are brought into the plant directly from the fields by truck and wagon, and in field boxes weighing from fifty to seventy pounds. They are unloaded by hand into a chute, and moved by gravity into a washer. In the washer are revolving plates and flowing water. After being washed, the tomatoes are carried by means of an elevator chain up to, and laid upon, a sorting table with a movable top. There the tomatoes are sorted by women standing on both sides of the table. Their duty is to cull out the imperfect tomatoes, and to remove the stems and cores from those that are usable. The tomatoes move from the sorting table to a mill, or crusher, equipped with revolving steel plates by which they are thoroughly crushed. From thence the product is pumped through a pipe into a cooker where it is cooked from twenty-five to forty minutes, dependent upon the water content of the tomatoes, which content varies with the seasons. After cooking, it is pumped through a pipe into a finishing machine, which removes the skins and extracts the seeds, and thence through another pipe to a filler where the cans are filled mechanically. The filled cans are then sealed and moved to a sterilizing vat where they are boiled in water for approximately fifteen minutes, after which they are packed for shipment.

*[Tomato Product Submitted to Chemist for Analysis]*

Six cans of the seized article were withdrawn and delivered to a chemist for

analysis. The analysis disclosed that the contents of the cans was a tomato product of approximately 6.5% salt-free tomato solids, containing no spice or other condiment. It is conceded by all parties that this analysis is correct.

*[Regulations To Define Tomato Products Introduced in Absence of Standard of Identity]*

As stated, it was conceded by the libelant that no regulation had been promulgated establishing any definition and standard of identity or quality for tomato sauce. Regulations of the Administrator defining tomato juice, tomato puree, and tomato paste, however, were introduced in evidence. These were of some value in aiding the Court to reach its conclusion in the case.

*[Regulation Requisites]*

It appears from these regulations that tomato juice is an unconcentrated liquid, extracted from mature tomatoes, with or without scalding, in the extraction of which heat may be applied by any method which does not add water thereto. Salt may be added. The regulation prescribes no minimum or maximum percentage of salt-free tomato solids content for tomato juice, but according to the testimony of Mr. John T. Knowles, of Libby, McNeill & Libby, canners of various products, hereinafter referred to, tomato juice should contain a per cent of such solids ranging from a minimum of 4½% to a maximum of from 7½% to 8%.

*[Tomato Puree Defined]*

Tomato puree, otherwise known as tomato pulp, according to the regulations, is a concentrated tomato product which may be seasoned with salt, but not otherwise, and which contains not less than 8.37% but less than 25% of salt-free tomato solids.

*[Tomato Paste Defined]*

And tomato paste is defined as a highly concentrated product which may at the option of the processor be seasoned with salt, spices or flavoring, but which contains not less than 25% of salt-free tomato solids.

*[Tomato Sauce Tested by Nine Expert Witnesses]*

The libelant, in order to sustain its contention that the product was misbranded, placed nine expert witnesses on the stand, and offered in evidence certain cans of standard brands of tomato sauce, and a number of labels from other cans. Some of the cans were labeled "Tomato Sauce" and



*U. S. v. 254 Cases et al. "Baby Brand Tomato Sauce"*

some of them "Tomato Sauce Spanish Style." A can of "Baby Brand Tomato Sauce" and certain cans of other brands were opened and exhibited to the Court, by whom they were tested by pouring and tasting.

*[Testimony of Expert Witnesses Reviewed]*

The expert witnesses were representatives from various occupations and professions having dealings with tomato sauce. We will briefly review their testimony:

Samuel Alfend, a chemist of the Food and Drug Administration with twenty-two years' experience, defined tomato sauce as a spiced, concentrated tomato product with a salt-free tomato solids content of not less than 8.37%. He stated that it is a tomato puree with spices added. He testified that he had analysed approximately ten well-known commercial brands of tomato sauce and found spices in all of them, and that all were materially higher in tomato solids content than the seized product. Eight of these brands are hereinafter referred to more specifically.

Dr. Robert A. Osborne, a chemist in the Food Division, Beverage Section, of the Food and Drug Administration, testified that it was a part of his duty to make investigations of tomato juices, sauces and other products; that he had analysed "Baby Brand Tomato Sauce" and would class it as a beverage rather than a sauce.

John T. Knowles, a chemist of twenty-two years' experience in charge of the general laboratory of Libby, McNeill & Libby, manufacturers of food products, of Chicago, Illinois, testified that a consumer expects a tomato sauce to be a heavy-bodied product with spices, salt, and sometimes sugar, added. He stated that it should have a body of more than 8.37% of salt-free tomato solids. He defined "Spanish Style Tomato Sauce" as a somewhat hotter sauce than ordinary tomato sauce, and stated that in some of the Spanish Style sauces finger peppers rather than other peppers were used, because of the fact that they were hotter.

Edward Fox, an Ohio manufacturer of tomato products, with twenty-seven years' experience, defined tomato sauce as a tomato puree plus sugar, salt and spices, with a content of not less than 8.37% of salt-free tomato solids.

A. W. Carswell, plant manager of the Loudon Packing Company, Terre Haute,

Indiana, with twenty-four years' experience in the canning business, gave the same definition of tomato sauce as that given by Mr. Fox.

A. A. Mayhugh, buyer and sales manager for Silbernagel Wholesale Grocer Company, Pine Bluff, Arkansas, with twenty-seven years' experience in the wholesale grocery business, during all of which time he handled tomato products, defined tomato sauce as a product of at least the consistency of puree (8.37% solids) with spice added.

Mrs. Philip H. Chauvin, a housewife of Little Rock, Arkansas, for sixteen years in charge of the Little Rock High School cafeteria, and recently director of the feeding units of the Arkansas Ordnance Plant at Jacksonville, Arkansas, testified that in purchasing tomato sauce she expected a product of reasonably thick consistency, flavored with spices, salt, and probably sugar, so that, for cooking purposes, nothing need be added; and that she did not consider an unspiced tomato product with a consistency considerably less than that of puree, a tomato sauce, and would not buy it as such.

*[Recipes for Tomato Sauce Reviewed]*

On cross-examination, recipes for tomato sauce taken from the "Good Housekeeping Cook Book," 1942 edition, published by Farrar & Rhinehart, "The Joy of Cooking," published by the Bobbs-Merrill Company, 1936, and "Soups, Sauces & Gravies," published by the J. B. Lippincott Company in 1939, were read to the witness, and she was questioned with respect thereto. These recipes provided for mixtures containing varying amounts of spices, all the way from "a speck" of pepper to a considerable amount of onions, celery, parsley, peppers, and other ingredients; the salt-free tomato solids content of which mixtures, however, appeared to be much below that of "tomato sauce" as defined by the expert witnesses for the libelant. The witness stated in effect that the sauces referred to in these cook books were distinctly home products, made from ingredients available to the housewife, and were not comparable to the canned tomato sauces sold generally on the market.

*[Tomato Sauce Defined by Experts]*

Robert A. Dare, a chef with twenty years' experience, who had also acted as buyer for the Service Club at Camp Robinson, Arkansas, defined tomato sauce as a puree with spices added.



Mrs. James Keatts, a lady in charge of the Tea Room of the Gus Glass Department Store, of Little Rock, Arkansas, for the past two years, whose qualifications as an expert were admitted by the claimant, testified that in her opinion tomato sauce is thickened tomatoes, seasoned and ready to use. She stated that it should be seasoned with spices and fats, and that her recipe called for onions also. She said that a commercial tomato product containing no spices and below the standard of ordinary tomato puree, would not be called tomato sauce by her.

[*Labeling of Cans Examined in Court*]

As stated, a can of "Baby Brand Tomato Sauce" was opened in the presence of the Court, who poured a part of the contents into a glass and tasted it. Cans labeled "Del Monte Brand Spanish Style Tomato Sauce," packed by Berout Richards Packing Corporation, San Francisco, California, "Sunny South Spanish Style Tomato Sauce," packed by Lee Aiken & Sons, McAllen, Texas, and "Sacramento Tomato Sauce," packed by Berout Richards Packing Company, of Sacramento, California, were likewise opened in the presence of and tasted and examined by the Court. Two of these, namely, the *Sacramento* and *Del Monte* brands, were referred to by Mr. Alfend as having been analysed by him, and according to his testimony the *Sacramento* contained 9.7% and the *Del Monte* 10% of salt-free tomato solids. The Court found from his examination that the *Baby Brand* product was wholesome, unspiced, but considerably less concentrated and thinner than the other three brands just referred to. The latter brands were highly spiced. It will have been noted that the *Del Monte* and *Sunny South* brands were labeled "Spanish Style." The *Sacramento* was not so labeled, but the word "Savory" appears in small letters on the label between the words "Sacramento" and "Tomato Sauce." The *Sunny South* label was not introduced in evidence. The *Del Monte* label has on it also the following words: "Del Monte Tomato Sauce—a unique cooking sauce, blended especially for cooking uses from vine-ripened tomatoes, salt, peppers and spices, according to the original Del Monte recipe." The *Sacramento* label has upon it the following additional language: "made from whole red ripe tomatoes, with added salt, onions, green peppers, chili pepper, garlic and cayenne."

In addition to the cans above mentioned, one unopened can of "Libby's Tomato Sauce," manufactured by Libby, McNeill & Libby, of San Francisco, California, was introduced in evidence. This is labeled: "Ingredients: tomato puree, salt, dextrose and spices."

There were also introduced in evidence labels from cans of:

"Monarch Spanish Style Tomato Sauce," manufactured by Reid, Murdock & Co., Chicago, Ill., and described as "made from whole ripe tomatoes with salt, pepper and spices";

"All Good Tomato Sauce Spanish Style," described as "blended from vine-ripened tomatoes, salt, pepper and spices," and canned by F. H. Ball & Co., Oakland, Calif.;

"Bestex Brand Tomato Sauce Spanish Style," packed by Harlingen Canning Co., of Harlingen, Texas, and described on the label as "made from whole tomatoes with added pepper, salt, cayenne, paprika, onion and garlic";

"Can-D-Lite Brand Spanish Style Tomato Sauce," packed by Su Mar Foods, Inc., Chicago, Illinois, and described as "made from ripe tomatoes, salt and spices";

"Topmost Spanish Style Tomato Sauce," distributed by General Grocer Co., of St. Louis, Mo., and labeled as composed of "tomato puree, salt, green peppers, onions, garlic, spices";

"Lady Luck Spanish Style Tomato Sauce," described on the label as "with salt, pepper and spices," and canned by Oakland Canning Company, Oakland, California, for United Food Products Co., San Francisco, California;

"Hunt's Supreme Quality Spanish Style Tomato Sauce," packed by Hunt Brothers Packing Company, San Francisco, California, and described as "made from whole ripe tomatoes, salt, sugar, pepper and spices added"; and

"Hunt's Supreme Quality Fancy Spanish Style Tomato Sauce," packed by the same company and described in like manner.

[*Percentages of Salt-Free Tomato Solids Found in One Brand Listed*]

Mr. Alfend analysed six of these last mentioned brands and found that they contained the following percentages of salt-free tomato solids:



*U. S. v. 254 Cases et al. "Baby Brand Tomato Sauce"*

Monarch .....	13.1%
Can-D-Lite .....	9.4%
Topmost .....	8.8%
Lady Luck .....	9.5%
Hunt's Supreme Quality ....	10.2%
Bestex .....	8.4%

*[Two Products Not Analysed]*

No analysis was made of the products labeled "Hunt's Supreme Quality Fancy Spanish Style Tomato Sauce," and "All Good Tomato Sauce Spanish Style."

*[Four Witnesses Testified for Claimant]*

Four witnesses testified on behalf of the claimant.

*[Witnesses' Testimony]*

R. Raspanti, a partner in the firm of Uddo & Taormina Company, claimant herein, testified that he was born in Palermo, Sicily; that he came to this country in 1913, and in 1914 established the canning factory at Crystal Springs, Mississippi, now owned by the claimant; that he had personally operated the cannery for the past thirteen years; that he thinks he was the first canner of tomato sauce in America; that his father operated a cannery in Palermo, using practically the same process and producing practically the same article as that produced by him, and that as a boy he learned the canning business while working in his father's plant; that his father's product was unsliced just as is his; that throughout the years a part of his pack has had the same consistency as that manufactured by his father, and a part a greater consistency; that he called the product "tomato sauce" when he came from the old country and he continued to do so for two or three years after beginning business, until he saw that "the trade was confused"; some of which would want tomato paste, others tomato puree, and some tomato sauce; so he changed the labels several times, all the while producing the same product, but giving it whatsoever name the trade desired. At the same time, however, as we understand his testimony, a part of his output was labeled tomato sauce. He stated that he continued to label some of his cans tomato puree and tomato paste until the Food and Drug Administration promulgated certain standards for puree and paste, at which time he discontinued the use of those terms, and from thence down to the present has labeled all of his output tomato sauce; that for two seasons he added spices to a part of his pack and labeled it "Tomato Sauce Spanish

Style," but he did not find it profitable and discontinued it; that in his opinion the seized product is plain tomato sauce, and that "Tomato Sauce Spanish Style" is tomato sauce with spices added; that 99% of his product is sold in Arkansas, Louisiana, Mississippi, and Western Tennessee; that at different periods he has marketed it in four and one-half, eight and ten-ounce cans; that he estimates he has sold over 100,000,000 cans in these four states since he has been in business; that he has had no complaints, has sold all he could produce, and that the product has been accepted by the trade as tomato sauce.

The witness testified further that he was familiar with cooking, liked to cook and knew a cook's viewpoint with respect to his product; that many cooks preferred *Baby Brand* to spiced brands, for the reason that spices could be added to suit the taste; that, for instance, some desire a spaghetti sauce without pepper, others with a small amount of salt, and some with more; that his "sauce" forms a foundation upon which any type of sauce can be built.

A. Glorioso, another witness on behalf of the claimant, stated that he owned a cannery at Crystal Springs, Mississippi, known as the Mississippi Canning Company, and also canneries in several other states, and at one time had owned another plant in Mississippi; that he had been in the canning business since 1915; that he, like Mr. Raspanti, was born in Palermo, Sicily; that for many years he was a competitor of the latter in Crystal Springs, manufacturing at that point an unsliced tomato product, similar to *Baby Brand*, the production of which has been discontinued; that his product, however, did not contain more than from 5.5% to 6% of salt-free tomato solids; that he sold practically all of this product, which he described as "tomato sauce," in New Orleans, in Mississippi, and in South America, and that his specialty was the South American business; that when he was actively canning this article he sold a yearly average of from ten to twelve million cans, and never had any complaints; that there was a time when the product was called paste, but it was not a paste; that in Mississippi now no one calls it sauce or puree, but that ninety-nine out of one hundred people call it tomato paste; that the consistency of the product is regulated by heating; that the longer it is on the fire the thicker it becomes; that everyone does not like a thickened tomato product, but some prefer



it thin; that the product is, in his opinion, a sauce, and is spiced by the flavor of its tomato content; that as a natural sauce it has an advantage over those spiced with peppers, etc., in that it can be used in preparing soup, whereas garlic, one of the ordinary constituents of the spiced product, is never used in soup, and that it can be used as a dressing for spaghettis and rices by those who prefer the tomato taste to a spiced flavor.

*[Canners' Use of "Spanish Style" Clarified]*

In response to a question as to why many of the canners use "Spanish Style" in describing their tomato sauce, the witness stated that it was because sweet peppers or hot peppers had been added; that the tendency is to add a certain amount of pepper and spice; and that one can easily change a tomato puree to a sauce by adding a slight amount of cayenne pepper, which would make the spiced puree a "Spanish Style" sauce.

*[Testimony of Salesmen]*

Allein Beall, Jr., testified that he had been in the food brokerage business, operating at Helena, Arkansas, and Clarksdale, Mississippi, for twenty-five years; that he had sold the *Baby Brand* line for the last eight or ten years; and handled the shipment seized in this action; that "Baby Brand Tomato Sauce" was branded "Puree" up until five or six years ago, but since then has been branded "Tomato Sauce," and has been so accepted by wholesalers in his area; and that he has had no complaint on account of lack of concentration or spices. He was asked by counsel for claimant to approximate how many cases of the product he had sold since he had been handling it. He stated that as puree and sauce he had probably sold all totalled 125,000 cases of 48 cans each, and that if it were available he could sell a large amount of the product at this time.

William Roy Glover testified that he was a member of the firm of Glover & Wilson, food brokers, of Little Rock, Arkansas, and had been in that business eighteen years; that he had handled "Baby Brand Tomato Sauce" for a period of from twelve to fifteen years; that he estimates that his annual sales of the brand would run anywhere from three to six thousand cases; that his trade territory is all of Arkansas except the extreme eastern portion, which is included in the Memphis and Helena areas; that he has never had any complaints from

anyone as to the quality, identity or nature of "Baby Brand Tomato Sauce"; that since the seizure in this case he has, at the request of counsel for claimant, made specific inquiry of four retail dealers as to whether the trade accepts this product as tomato sauce, and has been assured by all four of these dealers that such is the case; that, in fact, the dealers wanted to know when they could get more, and one of them said that it had consumer acceptance "just like Arm & Hammer Soda"; that he had also handled a line of spiced tomato sauces, but that the trade accepted *Baby Brand* ten to one over the other sauces, and that if it were possible to get substantial quantities of it at the present time, he could readily sell it; that the people with whom he has dealt "bought Baby Brand Tomato Sauce for what it is, namely, an unspiced, slightly concentrated tomato sauce." When asked upon cross-examination whether he was sure that this product had been sold on the market as tomato sauce for the past twelve years, he stated that he knew definitely that it had been on the market for six or seven years in ten-ounce cans similar to those seized; and he stated further that some time back there was a "Baby Brand Tomato Sauce" which had spices in it, and which was sold by the same company in similar cans and labeled "Spanish Style."

*[Sufficient Evidence that Tomato Sauce Is Misbranded]*

In our opinion, the proof on the part of the libelant clearly sustains its contention that the seized article is misbranded. There seems to be no question but that dealers in, and consumers of, tomato products generally throughout the United States consider tomato sauce to be a spiced product containing not less than 8.37% of salt-free tomato solids. This has been established to our satisfaction not only by the testimony of the expert witnesses (ranging all the way from housewives to chemists and manufacturers of tomato products) who testified for the libelant and who uniformly so defined tomato sauce, but also by the cans, and labels from cans, of standard brands of tomato sauce which have been introduced in evidence.

*[Product Fails To Meet Requirements for Tomato Sauce]*

The seized article fails to meet the requirements of tomato sauce in two particulars; it is not spiced, and it contains but 6.5% of salt-free tomato solids.



*U. S. v. 254 Cases et al. "Baby Brand Tomato Sauce"**[Claimant's Tomato Sauce Found Unspiced]*

With respect to its being unspiced, it is significant that of thirteen brands of tomato sauce introduced in evidence herein, only one—the seized product—was unspiced. It is true that A. Glorioso, one of claimant's witnesses, testified that at one time he manufactured a so-called unspiced tomato sauce in Mississippi, but the proof shows that he is no longer doing so.

*[Seized Tomato Product Not a Sauce]*

In our opinion, the seized product is not a sauce at all, as that term is generally used. Sauce has been defined as "a condiment or composition of condiments and appetizing ingredients eaten with foods as a relish; esp., a dressing for meat, fish, puddings, etc."; and a condiment as "something used to give a relish to food, and to gratify the taste; usually, a pungent and appetizing substance, as pepper or mustard; seasoning." Webster's New International Dictionary, Second Edition.

*[Meaning of "Spanish Style" Set Forth]*

Stress has been laid by claimant on the fact that most of the brands offered in evidence were labeled "Spanish Style Tomato Sauce," and an inference is drawn that there are two kinds of tomato sauce, plain or unspiced, and *Spanish Style* or spiced. It is true that most of the brands were labeled "Spanish Style," but two of the brands containing spices were not so labeled, and it is apparent from the testimony of various expert witnesses in the case that the words "Spanish Style" merely constitute an adjective phrase conveying the idea that the sauce is heavily spiced.

*[Ethical Question Involved]*

It may be argued that the objection to the goods on account of their not being spiced is a rather technical one, and that since no definite standard of identity or quality has been fixed, they should not be condemned on that account, especially since the label does not represent that the product is spiced, but, on the other hand, that it is "made from whole tomatoes." If this point were conceded, the claimant would not, in our judgment, be materially aided thereby, because it is also confronted with a deficiency in tomato solids content, which deficiency presents a most serious ethical question in as much as it reflects the difference in food value of the claimant's product as compared with the product which is gen-

erally understood throughout the United States as being tomato sauce.

*[Deficiencies of Claimant's Product]*

It was conceded in argument that the *Baby Brand* article sells for the same price per ounce as the other brands in evidence. Standard brands vary from 8.4% to 13.1% of salt-free tomato solids, whereas *Baby Brand* contains an average of only 6.5%. According to the evidence, tomato sauce must be at least of the minimum consistency of puree, which is not less than 8.37% of salt-free tomato solids. *Baby Brand* therefore lacks 1.87% of containing the minimum percentage of tomato solids required for tomato sauce. This is a deficiency of 22.35%—and we are here referring to the *minimum* solids requirement for tomato sauce. The evidence also shows that *Baby Brand* contains only tomato solids and the water from the natural tomato. Therefore, the housewife in spending one dollar for "Baby Brand Tomato Sauce" would get only 77.65 cents' worth of food, as compared with a full dollar's worth when she invests in genuine tomato sauce of the lowest concentration. And in this connection the proof shows that one of the standard brands of tomato sauce contains over twice the percentage of tomato solids as that found in *Baby Brand*.

*[General Public's Conception of Tomato Sauce Important]*

It is true that in four states and parts of states, namely, Louisiana, Arkansas, Mississippi, and western Tennessee, the claimant's product has been accepted by the consuming public as tomato sauce over a long period of time, but during at least the greater part of that same period standard brands of the spiced product have likewise been so accepted; and, after all, what we are concerned with here is, what do housewives, cooks, restaurateurs, and other buyers throughout the United States, understand tomato sauce to be; not what a part of the consuming public in four states only might consider it to be.

*[Product Not Misbranded Can Be Sold Anywhere]*

It has been argued that in view of the heavy sales of the seized product in the four states mentioned, consumers there will not be misled by the brand "Tomato Sauce," and that the consuming public elsewhere will not be deceived since practically all of claimant's output is sold in these states. The answer to this is that claimant can, if



it sees fit, sell its product anywhere in the country, if it is not misbranded, and, moreover, the population of the four states mentioned does not remain static, but is constantly changing, due to the influx of people from other sections of the country.

*[Acceptance of Claimant's Product in Four States Cannot Establish Criterion for Product Shipped in Interstate Commerce]*

Claimant's contention with respect to trade acceptance over a long period of time is weakened somewhat by the fact that up until the time the Administrator fixed the minimum standards for tomato puree and tomato paste, it had sold its product under those names as well as the name of tomato sauce. Conceding such acceptance, however, as stated, we do not feel that consumer acceptance in four states, alone, can establish a criterion for a food product shipped in interstate commerce.

*[Claimant's Product Identified as Tomato Juice]*

The seized article is more nearly a tomato juice than any other tomato product that has been discussed in this lawsuit. Dr. Osborne classed it as a beverage. He is an expert on beverages, being in charge of the Beverage Section of the Food Division of the Food and Drug Administration. We examined it and tasted it. It is somewhat heavier than the ordinary tomato juice that we use on our tables. It still may be a beverage, however. It is not a puree, due to its low concentration, and it is not a tomato sauce, which, according to the evidence in this case, is a puree with spices added. Not being a tomato sauce, it is misbranded.

*[Government's Claim of Misbranding Established by Satisfactory Evidence]*

The question of strict or liberal construction of the Act was argued at considerable length by counsel for claimant and for the libelant, and it was contended by the form-

er that since this case involved a libel by the Government to forfeit property of one of its citizens, the proof required must be of a degree higher than a mere preponderance, citing *Van Camp Sea Food Co., Inc. v. United States*, 3 Cir., 82 F. 2d 365. The libelant, on the other hand, contended that the rule of strict construction invoked by the claimant should not be applied, since the Federal Food, Drug, and Cosmetic Act was enacted to protect the public and should therefore be liberally construed, and cited *United States v. Research Laboratories, Inc.*, 9 Cir., 126 F. 2d 42, to sustain its position. It is not necessary for us to choose between these conflicting theories, since in our opinion the Government has established its claim of misbranding by clear and satisfactory evidence. The following language, however, used by the Supreme Court in *United States v. Ninety-Five Barrels of Vinegar*, 265 U. S. 438, 443, appears significant in this connection.

"It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. The statute applies to food, and the ingredients and substances contained therein. *It was enacted to enable purchasers to buy food for what it really is.*" (Citing cases.)

*[Claimant's Product Condemned]*

The seized product should be condemned, but, being a wholesome food, should not be destroyed. The order will be that the cans under seizure be sold by the Marshal after being properly labeled. The sale, however, may be avoided if the claimant will pay the costs of this proceeding and give bond conditioned that the article shall not be sold or disposed of contrary to law, as provided in Section 334 (d) of the Act.

*[Findings of Fact and Conclusions of Law]*

Findings of fact and conclusions of law made in accordance with this opinion are filed herewith.



UNITED STATES v. 738 CASES, MORE OR LESS, EACH  
CONTAINING 48 CARTONS OF AN ARTICLE  
LABELED IN PART "JIFFY-LOU  
VANILLA FLAVOR PUDDING"

United States District Court for the District of Arizona. No. Civ. 658-Phx.  
February 8, 1946. 71 F. Supp. 279.

The case involved seizure proceedings against cartons of pudding alleged to be misbranded under Section 403 (d). The court found that the container was of a size recognized by the public as a standard size for such commodities, and contained a standard amount of ingredients sufficient to make a standard amount of finished product and the amount of finished product expected by the consuming public.

Sections 304 (a), 403 (d), Federal Food, Drug, and Cosmetic Act.

While the commodity filled only approximately 55 per cent of the exterior container without allowance for space required by the inner removable package, the container used was sanitary, convenient to the user, and of a type reasonably necessary in packaging, handling, and utilizing the product sought to be condemned; the type of inner packaging used required the use of an outside container larger than the inner package; and the container was not so filled as to be misleading under Section 403 (d).

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

Section 403 (d) applies only to a container so made, formed, or filled as to be misleading in fact.

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

LING, District Judge: The issues made by the Amended Libel and the Answer thereto of Safeway Stores, Incorporated, having been heretofore tried by the Court, sitting without a jury, and the Court having heretofore made and entered its order determining said issues and directing the dismissal of said libel proceedings, the Court now makes the following Findings of Fact and Conclusions of Law:

**Finding of Fact**

**I**

That pursuant to a libel proceedings instituted by the United States District Attorney for the District of New Jersey in the United States District Court for said District of New Jersey, praying for the condemnation of the article hereinafter described as misbranded within the meaning of 21 U. S. C. 343 (d), and to the monition issued thereon, the United States Marshal for the said District of New Jersey attached 408 cases of merchandise, more or less, each containing 48 cartons of an article labeled in part "Jiffy-Lou Vanilla Flavor Pudding"; and thereafter and now holds said merchandise in his custody thereunder.

**II**

That thereafter Safeway Stores, Incorporated,

a Maryland corporation, intervening in said proceeding, made and filed its claim to said merchandise, in the manner and form required by law, claiming to be the true and bona fide sole owner of said 408 cases, more or less, of said merchandise.

**III**

That thereafter said Safeway Stores, Incorporated, as such claimant, deposited the sum of \$250.00 with the Clerk of said United States District Court for the District of New Jersey in lieu of a stipulation for claimant's costs, which said sum remains on deposit with the Clerk aforesaid.

**IV**

That thereafter claimant, Safeway Stores, Incorporated, filed its petition for removal of said proceedings pursuant to Section 304 of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, praying the removal thereof to a district of reasonable proximity to said claimant's principal place of business for trial.

**V**

That thereafter the said United States District Attorney for the District of New Jersey filed in the court and matter aforesaid an Amended Libel for Condemnation seeking the condemnation of 738 cases,



more or less, each containing 48 cartons of an article labeled in part "Jiffy-Lou Vanilla Flavor Pudding" upon the grounds and for the cause alleged in the original libel, pursuant to which said Amended Libel an Amended Monition was issued, directed to the aforesaid United States Marshal for the said District of New Jersey, commanding the attachment by said Marshal of the merchandise aforesaid, and pursuant to which said Marshal did attach said 738 cases, more or less, of said merchandise, and thereafter and now holds said merchandise in his custody thereunder.

## VI

That thereafter Safeway Stores, Incorporated, a Maryland corporation, intervening in said proceeding, made and filed its amended claim to said merchandise in the manner and form required by law, claiming to be the true and bona fide sole owner of said 738 cases, more or less, of the commodity aforesaid.

## VII

That thereafter said claimant filed its further Petition for Removal directed to said Libel and Amended Libel for Condemnation and to the Monitions issued thereon, which said petition was thereafter, and on the 26th day of February, 1945, granted by the said District Court for the District of New Jersey, Judge William J. Smith presiding, and said condemnation proceedings were ordered removed for trial to the United States District Court for the District of Arizona, at Phoenix, Arizona, as a district of reasonable proximity to the principal place of business of said claimant.

## VIII

That thereafter said cause was removed to this court and filed herein and within the time limited by law, as extended by proper order, from time to time, Safeway Stores, Incorporated, filed its Answer, claiming to be the owner of said merchandise and denying the same was misbranded and should be condemned, and the matter proceeded to trial upon the record and pleadings aforesaid.

## IX

That claimant, Safeway Stores, Incorporated, is the true and bona fide sole owner of the merchandise the subject of said Libel and Amended Libel and the Monition and Amended Monition issued thereon and now in the custody of the

United States Marshal for the District of New Jersey.

## X

That said 738 cases, more or less, of said merchandise was shipped, as alleged in the Libel and Amended Libel aforesaid, in interstate commerce, by claimant herein, and then was a food product subject to the provisions and requirements of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. 301, *et seq.*

## XI

### *[Description of Product in Issue]*

That the food product sought to be condemned herein is a preparation or formula containing ingredients which require the addition of a standard and recognized quantity of liquid to produce a food for human consumption, and said merchandise is not prepared or sold by claimant for use as food in the form sold; that said merchandise is sold by claimant for use as food after the addition of said liquids and after cooking.

## XII

### *[Description of Container in Issue]*

That the container used is of a size which is recognized by the general public as a standard size for this and similar commodities and contains a standard amount of ingredients sufficient to produce and make a standard amount of finished product and the amount of finished product expected by the consuming public; that said container plainly states on the outside thereof the weight of the ingredients contained therein and the fact that such ingredients will produce one pint of food when prepared for human consumption.

## XIII

That the container used for the commodity sought to be condemned is commonly and universally recognized as containing enough formula and ingredients to make a standard and publicly recognized recipe producing one pint of pudding; that such fact is known to the buying public generally, and there is no relationship between the size of the container used and factors and reasons causing the public to purchase the commodity involved.

## XIV

That, while said commodity fills only approximately about 55% of the exterior container without allowance for space required by the inner removable package, the con-



tainer used is sanitary, convenient to the user, and of a type reasonably necessary in packaging, handling and utilizing the product sought to be condemned; that the type of inner packaging used in packaging the commodity involved requires the use of an outer container larger than the inner package; that said container is not so filled as to be misleading within the meaning of subdivision (d), Section 343, 21 U. S. C., or otherwise, and said container and commodity does not otherwise violate said Federal Food, Drug, and Cosmetic Act of June 25, 1938.

### Conclusions of Law

#### I

That 21 U. S. C. 343 (d) applies only to a container so made, formed or filled as to be misleading in fact.

#### II

#### [Container Not Misleading]

That since the proof shows said container is not so made, formed or filled as to be misleading, the Libel and Amended Libel should be dismissed, the Monition and Amended Monition should be quashed, and the Clerk of the United States District Court for the District of New Jersey should be directed to refund to claimant the cost deposit made by claimant in lieu of a stipulation for costs in the sum of \$250.00 and on deposit with said Clerk, and the United States Marshal for the District of New Jersey should be directed to release and deliver said 738 cases, more or less, of said article labeled "Jiffy-Lou Vanilla Flavor Pudding" and that judgment should enter accordingly.

---

## UNITED STATES v. 43½ GROSS, MORE OR LESS, RUBBER PROPHYLACTICS LABELED IN PART "XCELLO'S PROPHYLACTICS," AND 112½ GROSS, MORE OR LESS, RUBBER PROPHYLACTICS LABELED IN PART "SILVER-TEX PROPHYLACTICS"

United States District Court for the District of Minnesota, Fourth Division.  
No. 1502 Civil. February 11, 1946. 65 F. Supp. 534.  
Affirmed, 159 F. 2d 881. See page 205.

In a seizure proceeding against a shipment of prophylactics alleged to be misbranded and adulterated because of the presence of holes, approximately 7.37 per cent of the prophylactics tested by the Government were found to be defective, but, of the entire shipment seized, a fraction of one per cent was definitely shown to be defective. The burden of proof rests upon the Government, but it does not follow that each individual item must be tested.

Sections 304 (a), 501 (c), 502 (a), Federal Food, Drug, and Cosmetic Act.

Inspection and condemnation on the basis of samples tested is clearly contemplated by the Act, and the cases seem to contemplate that the testing of samples is sufficient if the samples are representative ones. The samples in the instant case were held to be representative.

Sections 304 (a), 304 (c), Federal Food, Drug, and Cosmetic Act.

Although some of the articles were in all probability free from defects, there is a distinction between condemnation and the confiscation of goods. After the decree, the claimant can separate the good from the defective.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

The provisions of Section 304 (d) indicate an intent by Congress that part of a shipment would not violate the Act but would be subject to a decree of condemnation together with the defective merchandise.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.



Federal Food, Drug, and Cosmetic Act  
*U. S. v. 43½ Gross "Xcello's Prophylactics"*

The court is not required or permitted to establish any formula as to what tolerance or defects should be allowed, if any, in every type of libel proceeding before it determines that the Government has sustained the burden of proof as to any particular shipment.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act requires that it be interpreted liberally.

Title, Federal Food, Drug, and Cosmetic Act.

Even though, upon reinspection under Section 304 (d), the articles proceeded against would be rendered defective, the purposes of the Act cannot be relaxed merely because of such difficulty. The burden of separating the good from the bad, under the Section, should rest on the claimant.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Victor E. Anderson, U. S. Atty., and Clifford F. Hansen, Assistant U. S. Atty., St. Paul, Minn., for plaintiff.

Maurice Weinstein, Milwaukee, Wis., and Ralph Stacker, St. Paul, Minn. (of counsel), for defendant.

[*Nature of Proceeding*]

GUNNAR H. NORDBYE, Judge: A libel of information was filed against the goods described in the caption on the theory that they were adulterated within the meaning of 21 U. S. C. A. § 351 (c) and that they were misbranded within the meaning of 21 U. S. C. A. § 325 (a). The goods were labeled "Prophylactics" on the carton in which they were contained, and the Government contends that such labeling constitutes misbranding within the meaning of the Act. The articles consist of certain rubber devices sold ostensibly for the purpose of preventing transmission of venereal disease. The government witnesses testified that, of the Xcello brand, 180 were tested and 14 contained holes; that 228 of the Silver-Tex brand were tested and 16 contained holes. Medical witness testified that the defective devices would not serve as a means for the successful prevention of the transmission of venereal disease.

[*Pertinent Statutory Provisions*]

Section 351 provides:

"A drug or device shall be deemed to be adulterated—

"(c) If \* \* \* its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

Section 352 provides:

"A drug or device shall be deemed to be misbranded—

"(a) If its labelling is false or misleading in any particular."

[*Devices Were Misbranded*]

The government inspection has established that the devices tested were defective in the number indicated, and there can be no serious doubt that the strength and quality of these particular defective articles fell below that which they purported or were represented to possess. Furthermore, it seems clear that, being labeled "Prophylactics," there was misbranding within the meaning of the statute. These defective devices are not efficacious in furnishing protection from disease.

[*The Issue Involved*]

The problem presented, however, pertains to the right of the Government to condemn the entire shipment. It appears that on or about June 19, 1945, about 43½ gross of the Xcello brand and 112½ gross of the Silver-Tex brand were shipped from the manufacturer in Akron, Ohio, to a concern in Minneapolis. It is from this shipment that the samples were taken and the tests made as stated above. The Government took two samples—a pre-seizure and a post-seizure. While the method by which the first sample was taken is not entirely clear in the record, it does appear that, in taking the post-seizure samples, the Government took one dozen articles from each of the 36 gross cartons of Xcellos, and from the three gross so selected 72 samples were taken at random. Six, or about 8 per cent of the 72, were found to be defective. In the pre-seizure test of the Xcello brand, 108 were selected and 8 were found to be



defective, or about 8 per cent. The post-seizure samples of the Silver-Tex brand were obtained by substantially the same method of selection by which the Xcello post-seizure samples were selected. In the post-seizure test of this brand, 120 samples were taken; four or 3.33 per cent, were defective. In the pre-seizure test of this brand, 108 were tested and 12 were defective, or approximately 11.11 per cent. The average defects, therefore, of all the tests is approximately 7.37 per cent. But of the entire shipment seized, a fraction of one per cent is definitely shown to be defective, and claimant contends that the Government has failed to sustain the burden of proof which rests on it in these proceedings in its attempt to condemn the entire shipment. It should be pointed out that apparently the only practical tests which the government representatives are able to make with the facilities available to them results in the article's being rendered useless after the test has been made. Concededly, the burden of proof rests upon the Government. *United States v. 5 One-Pint Bottles, et al.*, (D. C. N. Y., 1934) 9 F. Supp. 990; *United States v. 11¼ Dozen Packages*, (D. C. N. Y., 1941) 40 F. Supp. 208. But it does not follow that each individual article in the shipment must be tested. Inspection and condemnation on the basis of samples tested is clearly contemplated by the Act. In fact, the Act speaks of samples and their availability for testing. 21 U. S. C. A. § 334 (c). And the cases seem to contemplate that testing of samples is sufficient if the samples are representative ones. *Andersen & Co. v. United States*, (9 C. C. A. 1922) 284 F. 542; *United States v. 200 Cases, et al.*, (D. C. Tex., 1923) 289 F. 157. No serious question is raised in this proceeding as to the samples taken being representative. But claimant contends that the Court cannot order the condemnation of good articles, and concededly some of the remaining articles are in all probability free from defects. However, in urging this contention, claimant fails to distinguish between condemnation and the confiscation or sale of goods. Condemnation only sustains the Government's position that the goods as they were composed in interstate shipment violate the provision and purpose of the Federal Food and Drug Act. After the decree, the claimant can separate the good from the defective if it posts a bond, and thereby will be able to retain the balance of the goods. 21 U. S. C. A. § 334 (d). The

very fact that part of the section of the Food and Drug Act which governs condemnation and confiscation procedure contains a section which permits the separation of the acceptable from the defective goods after condemnation indicates an intent and recognition by Congress that some of the shipment may not violate the Act, but nevertheless would be subject to a decree of condemnation together with the defective merchandise. In view of the fact that the tests which the government representatives have applied render the articles useless, it is highly improbable that the statute intended that only the defective articles are to be condemned. The impracticability of such a libel action is obvious and the impracticability of such a construction also seems clear. In effect, it would prevent application of the Act to many situations to which Congress intended it to be applied. But it is urged that the number of defectives are so low in proportion to the total number of articles involved in this proceeding that a grave injustice would result to the claimant if the entire shipment is condemned. Again, it may be reiterated that condemnation is not necessarily confiscation, and that representative sampling is permitted by the Act. Moreover, the Court is not required or permitted to establish any formula as to what tolerance of defects should be allowed, if any, in every type of libel proceeding before it determines that the Government has sustained the burden of proof as to any particular shipment. Suffice it to say that, on the state of the facts herein, and assuming that the same ratio of defectives would be found in the entire shipment, it would follow that over 1,500 defective articles would be found in this shipment. Such a number, if sold on the market, would constitute a potential menace to public health, and, in view of the claimed purpose and object of the devices, that is, the prevention of disease, are sufficient to sustain the libel proceedings herein.

[Federal Food and Drug Act Liberally  
Interpreted]

The purpose of the Federal Food and Drug Act requires that the Act be interpreted liberally. "One of the declared purposes of the Federal Food, Drug and Cosmetic Act is to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics. *United States v. Dotterweich*, 320 U. S.



277, 280, 64 S. Ct. 134; \* \* \* *United States v. 1851 Cartons, etc.*, (10 C. C. A., 1945) 146 F. 2d 760. Thereby Congress hoped to "prevent injury to the public health," *United States v. Research Laboratories*, (9 C. C. A., 1942) 126 F. 2d 42, by prohibiting "the sale of inferior for superior articles." *United States v. 200 Cases, etc.*, (D. C. Tex., 1923) 289 F. 157; and protecting the uninformed from buying an article which was different from what it purported to be. *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399, 409, 34 S. Ct. 337, 58 L. Ed. 658, L. R. A. 1915B, 774; *United States v. 5 One-Pint Bottles, etc.*, (D. C. N. Y., 1934) 9 F. Supp. 990. If claimant's contention were adopted here, this purpose could not be carried out, for the practical difficulties involved would permit defective articles to move in commerce and to be sold to uninformed persons without affording the protection represented.

[*Another Case Expressing Similar Views*]

The Circuit Court of Appeals for the Ninth Circuit expressed its views upon a similar problem with reference to food as follows:

"It is further argued that the court should not destroy 1,600 cases of good salmon because 400 cases of the same lot are found to be adulterated. In answer to this we need only say that destruction does not follow condemnation as a matter of course. Section 10 of the Act provides for the restoration of the goods on payment of the costs and the giving of a sufficient bond to the effect that the articles will not be sold or otherwise disposed of contrary to the provision of the Act. Under this provision the defendant in error may, and will doubtless be permitted to, separate the good from the bad, and the burden of so doing should rest upon it, and not upon the government, or the ultimate consumer. If it cannot do this, it is its own misfortune, and it must suffer the consequences. *Andersen & Co., v. United States*, (9 C. C. A., 1922) 284 F. 542, 545.

[*U. S. v. 200 Cases, etc., Is Unsound*]

*United States v. 200 Cases, etc.*, (D. C. Tex., 1923) 289 F. 157, seems contra to the

*Andersen* case. But it proceeds upon the theory that the shipment cannot be condemned unless every article therein has been shown to be defective. For the reasons noted above in discussing claimant's contention to the same effect, this case seems unsound.

[*Burden of Separation of Goods Is on Claimant*]

The claimant herein seems especially concerned, however, because it contends that, upon reinspection pursuant to the bonding procedure provided for in 21 U. S. C. A. § 334 (d), the articles will be rendered useless, or at least their quality and strength impaired by the wear occasioned by any further testing. But the purposes of the Act cannot be relaxed merely because of difficulties which may be encountered upon reinspection. The claimant's own testimony shows that these articles are inspected at the factory before shipment, and it contends that such methods of testing are the most modern known in this particular trade. No good reason is suggested why the same articles cannot be again subjected to the testing to which they were subjected at the factory before they entered the channels of interstate commerce. In any event, these goods are sent into commerce labeled "Prophylactics." The Act seeks to prevent the sale of articles labeled as prophylactics when in fact they are not. The burden of separating the good from the bad under these circumstances should rest on the claimant. Certainly, if the manufacturer desires to continue the labeling and representations as to the quality and strength of its product, it will have to contend with whatever hardships or inconveniences the violation of the law may entail.

[*Government Entitled to Judgment*]

It follows from the foregoing that the Government is entitled to findings of fact and conclusions of law in harmony with the foregoing, as prayed for in its libel of information, with the right of the claimant to proceed under Section 334 (d) in accordance with the provisions therein contained. An exception is allowed to the claimant.



BYRD, INTERVENOR, DOING BUSINESS AS NU-  
CHARME LABORATORIES v. UNITED STATES

United States Circuit Court of Appeals for the Fifth Circuit. No. 11539.

Decided March 19, 1946. 154 F. 2d 62.

Affirming 61 F. Supp. 850. See page 161. See 59 F. Supp. 284, page 149, and  
61 F. Supp. 847, page 159.

The promulgating authority granted to the Administrator is a quasi-legislative power. He is given a wide discretion and his judgment, if based on substantial evidence of record and within statutory and Constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.

Section 701 (e), Federal Food, Drug, and Cosmetic Act.

The Act contemplates that the Administrator shall not arbitrarily exercise power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied.

Section 701 (e), Federal Food, Drug, and Cosmetic Act.

Where notice of public hearing of the proposed issuance of a regulation on coal-tar colors in cosmetics was given, hearing had, findings of fact made from evidence of record, and the regulation duly promulgated, the regulation was not open to collateral attack, except upon Constitutional grounds, since the Act was fully complied with and provides for review by appealing the regulation to the proper circuit court of appeals.

Sections 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

The procedure provided by the Act, and complied with in the instant seizure action, met the test required by the due process clause of the Fifth Amendment.

Sections 304 (a), 701 (f), Federal Food, Drug, and Cosmetic Act.

Since evidence as to pernicious effect liable to be caused by the application of any coal-tar color to the orbital area was not controverted by any testimony of record, and at the hearings the Administrator had found that coal-tar colors are not harmless in the orbital area and may cause loss of sight, the quasi-legislative action of the Administrator in issuing a regulation that no coal-tar color should be issued for use in a product to be applied in the area of the eye was not arbitrary or capricious, but was the reasonable exercise of a sound judgment and discretion.

Sections 601 (a), 601 (e), 604, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Harry V. Booth and Charles B. Emery, Shreveport, La., and Phillip G. Alston, Texarkana, Ark., for appellant.

Malcolm F. Lafargue, U. S. Atty., and Wm. J. Fleniken, Asst. U. S. Atty., Shreveport, La., for appellee.

Before SIBLEY, HOLMES, and McCORD, Circuit Judges.

[*Previous Proceedings*]

HOLMES, Circuit Judge: These two libels *in rem* were filed by the United States against 3-7/12 dozen packages and 26 cartons, respectively, of Nu-Charme Perfected Brow Tint. They were disposed of on the pleadings pursuant to a stipulation of the

parties. These appeals were taken from judgments confiscating the property and ordering its destruction. For a statement of the facts pleaded and the issues presented, see the opinions of the court below in 59 F. Supp. 284, 61 F. Supp. 847, and 61 F. Supp. 850.



*[Issue Involved]*

It appears from the pleadings without contradiction that the property seized contains a poisonous and deleterious substance, namely, para-phenylene diamine, which is considered a coal-tar color since it is derived from coal-tar and imparts color when applied to other substances; but the appellant, doing business as Nu-Charme Laboratories, intervened as claimant and denied that the product might be injurious to users under the conditions of use prescribed in the labeling thereof. The sole issue upon the pleadings was and is whether the aforesaid consignments of eyebrow and eyelash dye, which had been shipped in interstate commerce for cosmetic use in the area of the eye, were adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.<sup>1</sup>

A cosmetic is deemed adulterated under said act if it is not a hair dye and bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations providing for the listing of coal-tar colors that are harmless for use in cosmetics.<sup>2</sup> It being undisputed that the cosmetics seized contain a coal-tar color, the appellant assails the administrator's action in banning all such colors for use in preparations applied in the orbital area.

*[Authority of the Administrator]*

The promulgating authority granted to the administrator is a quasi-legislative power.<sup>3</sup> He is given a wide discretion and his judgment, if based on substantial evidence of record and within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.<sup>4</sup> The statute contemplates that he shall not arbitrarily exercise his power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied.<sup>5</sup>

*[Regulation Not Subject to Collateral Attack]*

Section 371 (e) of the act authorizes the administrator to hold public hearings after appropriate notice thereof is given. Such

notice was given in this instance and published in the Federal Register as provided by law.<sup>6</sup> It set forth the proposal in general terms, and specified the time and place for the hearings to be held, which was not less than thirty days after the date of the notice.<sup>7</sup> The hearing was had, findings of fact were made from evidence of record, and the regulation was duly promulgated.<sup>8</sup> Appellant contends that the regulation promulgated by the administrator may be collaterally attacked in condemnation proceedings, but we agree with the trial court that it is not open to collateral attack, except upon constitutional grounds, since the statute was fully complied with in every respect and provides that the procedure for review of the action of the administrator shall be by appeal to the proper circuit court of appeals.<sup>9</sup>

*[Regulation in Accordance With Due Process]*

The regulation was promulgated according to the policy set forth in the act; the method prescribed was the listing of coal-tar colors found to be harmless, and certification of batches of such colors; a standard was furnished in prescribing that the regulation would list only such colors as were found to be harmless and suitable for use. Congress stated the general rule, and left to the administrator the duty of ascertaining what particular colors should be listed.<sup>10</sup> This procedure meets the test required by the due-process clause of the Fifth Amendment.

*[Appellant's Contention]*

Counsel for appellant stated that if the administrator could legally refuse to certify any coal-tar product for use in coloring eyebrows and eyelashes, then there would be no question but that the Government would be entitled to judgment. We agree with this statement and have examined the facts upon which the regulation was issued. The evidence as to the poisonous and pernicious effect liable to be caused by the application of any coal-tar color to the orbital area was not controverted by any direct and positive testimony of record. At the hearing on the proposed regulation for

<sup>1</sup> 21 U. S. C. A., Sec. 361(a)(e).

<sup>2</sup> 21 U. S. C. A., Secs. 361(e) and 364.

<sup>3</sup> 21 U. S. C. A., Sec. 364.

<sup>4</sup> *Security Admr. v. Quaker Oats Co.*, 318 U. S. 218, 228.

<sup>5</sup> *Twin City Milk Producers Ass'n v. McNutt*, 122 F. (2) 564.

<sup>6</sup> 44 U. S. C. A., Sec. 308.

<sup>7</sup> Federal Register, Vol. 4, No. 89, beginning on page 1922.

<sup>8</sup> 21 U. S. C. A., Sec. 371(e).

<sup>9</sup> 21 U. S. C. A., Sec. 371(f).

<sup>10</sup> 21 U. S. C. A., Sec. 364.



listing of colors suitable for use, the administrator found that coal-tar colors are not harmless for use in preparations applied in the orbital area, which includes the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeballs, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. He found that the application of coal-tar colors to this area may cause serious injury and even loss of sight. Thereupon, he issued the regulation that no coal-tar color should be certified for use in a product to be applied in the area of the eye. Such quasi-legislative action was not arbitrary or capricious but was the reasonable exercise of a sound judgment and discretion.

Affirmed.

### [Concurring Opinion]

SIBLEY, Circuit Judge: I agree to the judgment, but think it a more direct and satisfying thing to say simply that the Statute, 21 U. S. C. A., § 361 (e), positively declares that a cosmetic is adulterated if it is not a hair dye and bears or contains a coal tar color other than one from a batch that has been certified according to regulations as provided by § 364; and that this cosmetic is not a hair dye and does contain a coal tar color not from a certified batch. It cannot be sold and may be forfeited by the terms of the statute alone. If the Administrator ought under § 364 to make a list of harmless coal tar colors, and ought to include this one, some procedure must be resorted to other than to sell the cosmetic in defiance of the statute.

## UNITED STATES v. 935 CASES, MORE OR LESS, EACH CONTAINING 6 No. 10 CANS OF TOMATO PUREE

United States District Court for the Northern District of Ohio, Eastern Division. Civil No. 21218. April 16, 1946. 65 F. Supp. 503.

In a suit seeking condemnation of tomato puree on the ground that it was adulterated, it was reasonable to construe the word "article" in Section 304 to include an entire shipment of the same product regardless of the fact that some cases or cans were so labeled or coded as to indicate different dates of canning.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The "article," as used in the statute, is the product shipped in the cases or cans and not the individual cases or cans. If the samples taken by the Government are reasonably representative of the lot shipped—that is, taken at wide random from the entire shipment, it is sufficient to embrace the entire shipment in the condemnation.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The words "if it is otherwise unfit for food" in Section 402 (a)(3) do not modify, limit, or add any additional requirements of proof to the preceding words. There may be drawn a fair inference from the language of the Section that Congress considered that proof of filth or decomposition made the particular product unfit for food.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Difficulty in producing a product which is not decomposed furnishes no exception to the legislative requirement or inhibition.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The fact that a product cannot be prepared and shipped except in a decomposed state cannot justify permitting it to be transported, considering the plain language and purpose of the Act; nor are conditions of weather or methods of canning important if the product is found to be decomposed following interstate shipment.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.



The Act supersedes any earlier regulation of the Administrator, and while recognition of tolerances adopted by the Administrator is to be taken into account, the evidence showed adulteration in excess of the tolerances adopted.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Section 306 does not directly authorize exemptions but specifically gives the Administrator a discretion not to report or prosecute minor violations.

Section 306, Federal Food, Drug, and Cosmetic Act.

Section 405 gives the Administrator the power to promulgate regulations exempting certain requirements, and Section 406 authorizes regulations for tolerances in respect of poisonous ingredients. No such provision is provided with respect to Section 402 (a)(3).

Sections 402 (a), 405, 406 (a), 406 (b), Federal Food, Drug, and Cosmetic Act.

The Act must be interpreted liberally in the interest of the Congressional purpose to prohibit the transportation of adulterated foods in interstate commerce.

Title, Federal Food, Drug, and Cosmetic Act.

After entry of a decree of condemnation, the claimant might have the benefit of the provisions of Section 304 (d).

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Don C. Miller, U. S. Attorney, Cleveland, Ohio, for plaintiff.

Edwin H. Chaney, Cleveland, Ohio, and Bachelder & Bachelder, Indianapolis, Indiana, for defendant.

#### [*Nature of Proceedings*]

JONES, J.: The United States, by amended complaint, seeks to condemn 935 cases, more or less, of tomato puree shipped in interstate commerce by the Ladoga Canning Company, Lebanon, Ind., as consignor to the Weidman Company in Cleveland, as consignee.

Several samples of the tomato puree were seized and examined by the Food and Drug Administrator in the warehouse or store-room of the consignee.

The consignor has answered and while admitting certain procedural allegations denies the charges respecting the adulterated character of the tomato puree; denies that it is subject to seizure and confiscation and denies that it was shipped contrary to the jurisdiction of the United States and this Court.

#### [*Questions at Issue*]

In view of certain stipulations and the fact that findings and conclusions probably later will be presented for adoption it seems unnecessary to review or summarize the evidence, but only to set down the Court's consideration of and conclusions upon the issues presented.

In general, two main questions require response. First, were the samples seized representative of the article or product shipped in interstate commerce, and, second, does the evidence support the Government's charge that the tomato puree should be condemned as being adulterated within the meaning of Section 342 (a)(3) of Title 21, United States Code.

#### [*Representative Samples Taken*]

It seems reasonable to construe the jurisdictional and procedural statute (Section 334) and the word "article" used therein to include an entire shipment of the same product regardless of the fact that some cases or cans of the product in the shipment were so labeled or coded by the shipper as to indicate different dates of canning. I think the "article", as used in the statute, is the product shipped in the cases or cans and not the individual cases or cans. It would be impractical for the Government to examine samples from each case or can in the shipment on the theory that each case or can was an "article" in the sense of the statute. If the samples are reasonably representative of the lot shipped,—that is, taken at wide random from the entire shipment it is in my opinion sufficient to embrace the entire shipment in the condemnation.



*[Construction of the Statute]*

As to the question of the construction of the statute claimed for by the defendant during the trial,—that the words “if it is otherwise unfit for food” modify, limit or add any additional requirement of proof to the preceding words, I do not so interpret the language even though one may concede that the Congress, to the extent of its power, was by law intending to protect the public from food unfit for human consumption. On the contrary, while I think that it is not compelled or essential, there may be drawn a fair inference from the language that Congress considered that proof of the condition described made the particular article or product unfit for food.

*[Puree Was in a Substantial State of Decomposition]*

The evidence of the Government is that upon examination the samples taken show a substantial state of decomposition of the puree due to the presence of an excessive mold count, rot fragments, fly eggs and fly maggots and that this condition undoubtedly was due to the use of rotten tomatoes, since no one asserts that such condition likely could come into existence after sealing of the cans.

*[Tolerances]*

The defendant offered testimony to show the care with which its tomato puree was prepared for canning and also evidence to support its claim that the product in question can not, under the most careful supervision, escape entirely having some substance such as the Government claims existed in the samples; that the Administrator of the Food and Drug Act recognized this situation and circulated certain information respecting tolerances which would be recognized in the determination of whether the particular product came within the requirements of the statute. However that may be, difficulty in producing a product which is not in whole or in part decomposed in the sense of the statute furnishes no exception to the legislative requirement or inhibition. The fact that a product can not be prepared and shipped in interstate commerce except in a decomposed or rotted state certainly can not justify permitting it so to be transported considering the plain language and purpose of the statute; nor are conditions of weather or methods of canning important if the product is found to be decomposed and rotten upon examination following interstate shipment. These

considerations, as they seem to me, are not entirely to be waved aside by the fact that certain tolerances or allowances may have been recognized by the Food and Drug Administrator in the administration of the statute. If the product was under the evidence in a state of substantial decomposition and rotten, as those terms are well understood, that ends their right to interstate shipment and condemnation is in order.

*[Decomposition in Excess of Tolerances Adopted]*

The present statute supersedes any earlier regulation of the Food and Drug Administrator and while recognition of practices or tolerances adopted by the Administrator is to be taken into account and given due weight in applying the statute, the fact remains that here the evidence, in my view, shows an excess of substantial parts above the tolerances adopted, and it must be borne in mind that Section 336 of the Act does not directly authorize exemptions but specifically gives the Administrator a discretion not to report or prosecute minor violations.

*[No Provision for Tolerances Under Section 402 (a) (3)]*

That this is a conclusion rightly to be reached will be understood by reference to Section 345, wherein the Administrator is given power to promulgate regulations exempting certain requirements, and Section 346 authorizes regulations for tolerances in respect of poisonous ingredients. No such provision for regulation making exemptions, or for tolerating unavoidable ingredients is provided with respect to Section 342 (a) (3).

*[Microscopic Procedure More Dependable Than Taste or Smell]*

Nor am I impressed with the testimony that the variable sense of smell and taste is more dependable in detecting rot than the microscopic procedure adopted by the Government. Certainly the question of adulteration would rest upon tenuous ground if reliance or conclusion as to the character of the product shipped were bottomed upon conflicting evidence as to the smell or taste of the article sought to be condemned.

It is probably true that there will be a difference of opinion even under the microscopic procedure but for the want of a more reliable test it seems reasonable to accept such results depending, of course, upon the Court's conclusion as to the credibility of the witnesses testifying and giving their opinions upon that subject.



## [Act Must Be Interpreted Liberally]

The Act must be interpreted liberally in the interest of the congressional purpose to prohibit the transportation of adulterated foods in interstate commerce. In my judgment the Government has sustained the burden of proof and it follows from what has been said that condemnation of the en-

tire shipment of tomato puree must be ordered.

Proposed findings and conclusions may be submitted for approval and adoption accordingly.

After entry of a decree carrying into effect the judgment of the Court the defendant, or condemnee, may have the benefit of the provisions of Section 334 (d).

**UNITED STATES v. 14 CARTONS, MORE OR LESS,  
Each Containing 24 Packages, of an Article Labeled In Part  
as Follows: "AYDS Candy Contains Dextrose, Corn  
Syrup, Sugar, Condensed Whole and Skimmed Milk,  
Vegetable Oil, Soya Flour, Malt Syrup, Pow-  
dered Egg Yolk, Powdered Carrots, Salt,  
Imitation Vanilla Flavor . . . ."**

United States District Court for the Eastern District of Missouri,  
Eastern Division. No. 3736. June 10, 1946.

Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act,  
Foods (No. 12862) Issued February 1949.

Seizure proceedings were instituted against a product recommended for body weight reduction on the ground that it was misbranded under Section 403 (a). The claimant pleaded *res judicata*, based on an order issued by the Federal Trade Commission, which had been set aside by a circuit court of appeals, with respect to advertising disseminated on behalf of the product. What was charged to be false before the Commission was held to be substantially the same as charged in the libel.

Sections 304 (a), 403 (a), Federal Food, Drug, and Cosmetic Act.

It would be an incongruous situation if that which was not false advertising before one agency of the Federal Government were held to be false advertising before another; the Government's position was therefore contrary to the holding in *Lee v. Federal Trade Commission*, 113 F. (2d) 583 (C C A-8), and *United States v. Willard Tablet Co.*, 141 F. (2d) 141 (C C A-7).

Sections 304 (a), 403 (a), Federal Food, Drug, and Cosmetic Act.

**Memorandum Opinion**

HULEN, RUBEN M., Judge: This is a libel case. Plaintiff would confiscate fourteen cartons of Ayds Candy, a product recommended for weight reduction, because misbranded under Title 21, U. S. C., Section 343 (a). The Carlay Company claims ownership of the product. Claimant's answer (second defense) presents a plea of *res adjudicata*, that

"all of the issues set forth in the libel herein with respect to all printed matters and articles described and set forth in the libel and the right of the libelant to libel the same, have been heretofore determined and adjudicated by the Federal Trade Commission, an agency of the United States of America of co-ordinate authority with this honorable Court, in a proceeding entitled 'In the matter of the Carlay Company, a corporation, Federal Trade Commission Docket No. 4898 (1944),' and in which proceeding this

claimant was party respondent and the United States of America, acting through the Federal Trade Commission was party complainant, and in which proceeding the truth or falsity of the statements alleged in this libel to constitute misbranding were fully adjudicated in favor of this claimant, and in which the order issued by the Federal Trade Commission was appealed to the United States Circuit Court of Appeals for the Seventh Circuit, on a Petition for Review of Order of the Federal Trade Commission; \* \* \*

Both parties request ruling on this issue prior to trial of cause on its merits and same is now before the Court.

The package in which the product is sold, the printed matter on it and accompanying it, constitute plaintiff's case. Claimant offered Complaint of the Federal Trade Commission, order of Federal Trade Commission, Finding as to the Facts and Conclusions of the Commission, proceedings before



the Federal Trade Commission, and Exhibits offered by Claimant in Federal Trade Commission Case, Docket Number 4898, being the case prosecuted by the Commission against claimant.

[*Advertising Disseminated*]

The question before this Court is, was the main underlying issue in the case before the Federal Trade Commission the same as presented by the libel? The Commission's complaint charged claimant disseminated false advertising concerning their product for the purpose of inducing its purchase, the statements contained in circulars, leaflets, pamphlets and other advertising literature being:

"Many overweights praise the Ayds Candy reducing plan. It is easy. It is pleasant. No drugs. No exercising. It is usually effective where overweight is caused by over-nutrition. One or two delicious pieces eaten just before each meal \* \* \* and Ayds Candy curbs the craving for rich, fattening foods. Ayds contain vitamins A, B, and D and other essential nutrients. The diet is reduced automatically without the usual effort \* \* \* without weakening effects \* \* \* without hunger pangs.

"Many lose weight by 'Eat Candy' plan. Delicious Ayds Candy, eaten as directed by Ayds plan, curbs appetite for fattening foods.

"Ayds plan calls for no exercising. Many simply eat this delicious candy to curb their appetites for rich, fattening foods. Ayds plan is effective only in cases of overweight due to over-indulgence in eating, which includes most overweight people. Ayds Candy helps supply Vitamins A, B and D to prevent deficiencies that might occur due to lessened appetite.

"Would you like to lose up to 10 lbs. in 5 days? Try this New Home Lemon Juice Recipe Way to lose ugly fat! Here's marvelous news for women who are overweight. Now you can make a reducing supplement right in your own kitchen, to help you lose those ugly, unwanted pounds! It's so simple—so easy—and so effective. Some lose as much as 10 pounds in their first 5 days using this Plan! You never starve yourself. You use no drugs. You take no laxatives. You take no more exercise than you are accustomed to take. You eat plenty of healthful, satisfying foods. Yet you lose weight.

"Why be fat? Here's an amazing, Easy Way to Lose Weight. No starvation diet. No strenuous exercises. Everywhere in

America women are praising this simple, new way to lose ugly, unwanted pounds. By this easy plan many an overweight has been able to regain a more slender, more graceful figure. Many Now Eat Candy While They Grow Thin. It's so easy, you just eat one or two delicious pieces of Ayds Candy, with a glass of water before meals. This encourages you not to eat the rich, fattening foods, high in calories. You eat plenty—never go hungry! You don't cut out sweets and starchy foods. You just cut them down. You really *enjoy* reducing by this plan."

"The Eat Candy plan \* \* \* now eat candy and grow thin—new, easy plan.

"You never starve yourself. You eat plenty of healthful, satisfying foods.

"I lose 42 pounds in 60 days.

"You can lose ugly pounds and have a slender, graceful figure. No dangerous dieting. No drugs. No exercising. You simply eat this pure delicious food candy as directed and grow thin.

"Don't worry about those extra pounds. Many lose weight by new plan—eat candy every day.

"At last I wear size sixteen again! Lost 36 pounds without exercising—using Ayds plan and candy."

The charge was that by these statements, "all of which purport to be descriptive of the weight reducing properties" of claimants' product, claimants have represented that the use of "Ayds" and claimants' "plans" presents a new, easy way to reduce excess fat without dieting or exercise; "that the use of Ayds candy plays a significant and important part in the reducing plan offered by respondents; that the use of Ayds Candy will curb or dull the appetite for fattening foods, and that respondents' plans for reducing will result in the loss of excess weight in an easy, pleasant way without the necessity of strict dieting." Further charge was that the "plans" are not revealed to the purchaser before the purchase and the purchaser is led to believe through such "concealment" of the actual facts, that the only essential requirement, in order to obtain a reduction in weight, is the eating of a few pieces of the Ayds Candy before meals, when in fact a "severely restricted low calorie diet in addition to the use of respondents' product" is required.

[*Commission's Complaint*]

The Commission's Complaint charges (1) the statements (quoted above) to be false and misleading, and (2) the plans to be



deceptive. The particulars in which the statements and plans are misleading and false are set forth in detail:

"The Ayds play no significant role in the reducing program, their only function being to furnish some degree of vitamin and mineral supplementation for a reducing diet. The use of Ayds is not a new, easy way to reduce excess weight, but on the contrary it is necessary for the individual to follow a rigidly restricted dietary program. There is nothing easy about either the selection of, or adherence to, such a diet. \* \* \* The effect of Ayds upon the appetite is only temporary, and does not curb or dull the appetite or mitigate the pangs of hunger between meals. In order to be successful in reducing weight it is still necessary for the user to follow a rigidly restricted, low calorie diet, with all the discomforts and annoyances which are inherent in such diets. Moreover, such low calorie diets ordinarily supply sufficient quantities of essential nutritive elements, including proteins, vitamins and minerals, without the necessity of supplementing them by Ayds or other vitamin-enriched products.

"Any loss of weight that may be experienced by a person following the regimen advocated by respondents is due primarily to the restricted diet and not to the Ayds. Furthermore, respondents' representation as to loss of weight that may be expected by the use of their reducing methods are grossly exaggerated."

The Commission sustained the charges. Its findings conclude:

"Through the use of these statements and others of a similar nature, respondents have represented, directly or by implication, that the use of their candy and plan provides an easy way or method whereby excess weight may be removed from the body, and that such reduction in weight is effected without the necessity of restricting the diet.

"\* \* \* Respondents' plan for the removal of excess weight calls for the eating of one or two pieces of the candy before each meal and the observance of one of three restricted diets prescribed by respondents in the printed directions enclosed in each box of candy. Respondents' theory as to the part played by the candy in the weight reducing program is that the eating of the candy curbs the appetite, with the result that less food is eaten. The only virtue claimed by respondents for the vitamins and minerals in the candy is that they afford some protection against any nutritional deficiency which might result from the purported decrease in the food intake.

"As in the case of any sweet, the eating of respondents' candy immediately preceding a meal may to some extent curb or dull the appetite and make it somewhat easier to refrain from overeating at that particular meal. This effect, however, is only temporary; the desire for food will soon return, and unless such desire is restrained and the diet adhered to, the effort to reduce weight will result in failure.

"In short, any reduction in weight following the use of respondents' plan results from the adherence to the diet prescribed by respondents and not from the use of the candy. One following the diet would lose weight regardless of whether the candy is used or not, and the use of the candy without adherence to the diet would prove ineffectual.

"The removal of excess weight from the body, therefore, cannot be accomplished through the use of respondents' candy and plan without the necessity of dieting. On the contrary, respondents' plan contemplates the adherence to a low caloric diet, and such adherence is in fact essential. Nor is the use of the plan 'easy' as claimed by respondents. The adherence to restricted diets such as are prescribed by respondents is usually a difficult matter, particularly for individuals who are overweight, and require the exercise of an unusual amount of will power and self-restraint.

"\* \* \* The Commission therefore finds that the representations made by respondents with respect to their candy and to their plan for the removal of excess weight, as set forth in paragraphs three and four hereof, are erroneous and misleading and constitute false advertisements."

[Holding of Circuit Court  
of Appeals]

On review, the Circuit Court of Appeals, in *Carlay et al. v. Federal Trade Commission*, (7th C. C. A. February 15, 1946) 153 F. (2d) 493, ruled:

"There is no evidence in this record to support a finding that it is necessary, in order to follow the suggested plan, that the user adhere to a restricted diet. The facts are plain; it being undisputed that eating candy before meals curbs the appetite, lessens intake of food and involves no restriction of diet but automatically restrains the desire for food. This, we think, is all that petitioners have ever claimed; this, we think, is all that their advertising represents. There is absolute absence of any deceptive representation.



It follows that *there is lack of substantial evidence* to support the findings that a rigorous or restricted diet is necessary.

\* \* \*

"The Commission says that carrying the plan into execution is not 'easy.' The term obviously is one of comparative or relative connotation. Whether one plan is easy and another hard, whether one is easier than another, whether one is simple and another intricate, are all questions of comparative character and quality. The statement of practically all the witnesses is that the plan is easy and simple, and we think the only inference possible to draw from the undisputed facts leads necessarily to the conclusion that the plan is not a complicated one, but rather a relatively easy one involving no drugs, no restricted or rigorous diet; that its workings are simple in that it is only necessary for the user to eat the candy before meals and thus curb his desire for food, resulting not in the necessity of exercise of will power in refraining from consumption of certain foods, but in less desire for and less intake of all kinds of foods. \* \* \* *Consequently there was nothing deceptive in the advertising in this respect.*

\* \* \*

"Respondent urges that inasmuch as the details of the plan were contained only in the pamphlet inclosed in the candy box, the advertisements were deceptive in that they failed to advise the reader that the plan involved taking less food. Respondent terms this a restricted diet but, as we have seen in truth and in fact it is not a matter of dieting so much as the eating of sweet food to reduce the desire for food of higher calories. As we have observed, each of the advertisements refers to a plan. Anyone who reads them knows that eating the candy was to be accompanied by a suggested plan and that the candy and the plan together constituted the entire helpful contribution. When the reader obtained his candy and perused the plan, of which he had been given notice, he learned not that the advertisement was wrong but merely that the plan coincided with what the advertising told him, when to eat the candy, and what the purpose was in eating it." (Emphasis added.)

#### [Specifications of Misbranding]

The libel charges misbranding in that statements and certain "leaflets" which are attached to the libel as "Exhibit A," are false in that such statements and designs represent and suggest and create in the minds of the reader thereof the impression

that consumption of the article is effective (1) to cause loss of body fat and a reduction of body weight, (2) to enable the user to have a slender, more graceful figure, (3) to accomplish such a result quickly, easily, pleasantly, and without conscious dieting, (4) to curb the appetite and unconsciously train the user to reduce his food intake so that his weight, once reduced will not increase, (5) to enable the user to look better, feel better and younger and appear lovely, (6) to supply minerals and vitamins in proper amounts not only to prevent disease but enough for buoyant health, (7) to build up resistance of the body to disease by reason of its Vitamin A content, (8) and to help to maintain pep and energy and continued good health; whereas, consumption of the article is not effective for such purposes.

#### [Underlying Issue the Same]

When the specification of misbranding in the libel are compared with the Commission's Complaint, its findings and conclusions, and the ruling of the Circuit Court of Appeals in the *Carlay* case, we find that what was charged to be false before the Commission is substantially the same as charged in the libel. The libel couches its charge in different language, in some respects, from the Commission's complaint, but we cannot escape the conclusion that the underlying issue in the two proceedings is the same. The advertising matter used by claimant and relied upon by plaintiff to sustain its libel is the same advertising matter relied upon by the Commission to sustain its case. Thus libelant in effect admits that the basis of its case is the same evidence as was presented before the Commission.

#### [Plaintiff's Position Contrary to Lee Company Case]

Plaintiff would avoid the effect of the decision of the Court of Appeals in the Commission's case, on four grounds:

"(1) such (to hold a ruling in a Federal Trade Commission case *res adjudicata* in a libel proceeding) was not the intent of Congress;

"(2) it (such a holding) would be against public policy;

"(3) the order of the Federal Trade Commission even when affirmed, modified or set aside by the Circuit Court of Appeals does not possess the element of finality to support a plea of *res adjudicata*; and

"(4) there is no mutuality of estoppel." (Plaintiff's brief, page 38.)



Not included in this summary, it is also urged by plaintiff that the two proceedings under consideration are different. The proceeding before the Commission is "designed to restrain the unlawful advertising of 'Ayds Candy,' while the latter (libel) seeks the condemnation of a shipment of the product." Both proceedings are based on the same alleged false advertising. It would be an incongruous situation if that which was not false advertising before one Department of the Federal Government were held to be false advertising before another, on the hypothesis that in the one case the Government was only seeking to restrain the advertising, while in the other the Government was confiscating the product advertised. Government regulations, of necessity, have become complex in their nature, but this Court is unwilling to approve procedure of the character now contended for by the Government. Plaintiff's position, in our judgment, is contrary to the ruling of the Court of Appeals for the Eighth Circuit. In *George H. Lee Company v. Federal Trade Commission*, 113 F. (2d) 583, the Federal Trade Commission had proceeded against the appellant, charging false and misleading representations in the sale of "gizzard capsules." In a libel proceeding involving the same charge of falsity in advertising, the trial court resolved the issue in favor of the petitioner and dismissed the proceeding, from which no appeal was taken. The petitioner, being unsuccessful in its plea of *res adjudicata* before the Commission, was sustained by the Court of Appeals. The Court said:

"Where the underlying issue in two suits is the same, the adjudication of the issue in the first suit is determinative of the same issue in the second suit. \* \* \* There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the government. \* \* \* Where a suit binds the United States, it binds its subordinate officials. \* \* \* The United States may not relitigate the same issue in successive libel proceedings involving different quantities of the same product (*George H. Lee v. United States*, 9 Cir., 41 F. 2d 460), nor may it relitigate the same issue in any proceeding in which the parties are the same and the product is the same. The

rule is 'that a right, question, or fact distinctly put in issue, and directly determined by a court of competent jurisdiction, as a ground of recovery, cannot be disputed in a subsequent suit between the same parties or their privies; and even if the second suit is for a different cause of action, the right, question, or fact once so determined must, as between the same parties or their privies, be taken as conclusively established, so long as the judgment in the first suit remains unmodified.

"If the question of the falsity of the representations of the petitioner contained on its labels and circulars had been determined adversely to the petitioner in the libel proceeding, it could not have been heard to say in the proceedings instituted by the Commission that such representations were true. By the same token, the United States and its instrumentality, the Commission, were not after the decree in the libel proceeding, entitled to say that the representations made by the petitioner which had been finally adjudged not to be false, were in fact false. The government had had its full day in court on that issue, had lost its case, and could not collaterally attack, either directly or indirectly, the decree entered against it."

[*The Willard Case*]

In *United States v. Willard Tablet Company*, (7th C. C. A.) 141 F. (2d) 141, the United States instituted libel proceedings for condemnation of a quantity of Willard tablets on the ground that the labeling was false. The claimant there, as here, answered, setting up a plea of *res adjudicata*, based upon a prior proceeding before the Federal Trade Commission, where the charge was dismissed. The plea of *res adjudicata* was sustained in the trial court and affirmed on appeal, the Court citing the *Lee* case as authority for its ruling.

These two cases, one on an order of the Commission in which a judgment in a libel proceeding was successfully interposed on a plea of *res adjudicata*, and the other a libel in which an order on a Commission ruling was successfully interposed as *res adjudicata*, in our opinion disposed of the question presented by the record in this case and the points urged by plaintiff.

Order will go accordingly.



UNITED STATES v. FIVE CASES, MORE OR LESS, Each  
Containing One Demijohn, 5-Gallon Size, 9 Cases, More or  
Less, Each Containing 6 Bottles, One-Half Gallon Size,  
and 13 Cases, More or Less, Each Containing 12  
Bottles, One-Half Gallon Size of "CAPON  
SPRINGS WATER"

United States Circuit Court of Appeals for the Second Circuit. No. 286,  
Docket 20180. July 17, 1946. 156 F. 2d 493.  
Reversing 62 F. Supp. 736. See page 141.

In seizure proceedings against a product alleged to be misbranded because of false therapeutic claims, a prior adjudication in favor of the claimant under the Food and Drugs Act of 1906 that there was no fraud in the labeling of the product was held not to be a bar to the instant suit, since under the predecessor statute it was necessary to prove fraud.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The Federal Trade Commission had determined, prior to the instant suit, that the use of claimant's product "alone" would not cure the diseases mentioned. Such a finding was not the equivalent of a finding that the product had curative effects when not used alone, and did not constitute *res judicata* or an estoppel by judgment against the Government in the instant libel suit.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Under any possible theory, the former decision of the Commission that the use of the product "alone" would cure the various diseases was a finding of an ultimate fact which could not be used as a "*mediate datum*" in the present proceeding.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The remedies under the Federal Trade Commission Act and the Federal Food, Drug, and Cosmetic Act are cumulative and not exclusive.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

John F. X. McGohey, U. S. Attorney (Stanley H. Lowell, Vincent A. Kleinfeld and James B. Goding, of counsel), for plaintiff.

Horace M. Gray, for claimant.

Before L. HAND, AUGUSTUS N. HAND and CLARK, Circuit Judges.

[Nature of Proceeding]

AUGUSTUS N. HAND, Circuit Judge: This is a libel *in rem* brought under the Food, Drug, and Cosmetic Act based upon the alleged misbranding of "Capon Springs Water." The District Court dismissed the libel upon defenses of *res judicata* based upon two prior proceedings. The "Capon Springs Water" was alleged to be misbranded because of the following statement which appears on the bottle labels:

"Rebuilds as it Cleanses \* \* \*

"The Indians Called It Ca-Ca-Pa-On—  
'Health Water' \* \* \*

"Known to physicians as alkaline, because it contains by nature those elements needed to counteract *acidity*.

"\* \* \* beneficial in restoring the normal activity of the kidneys and bowels.

"Use According To A Natural Law of  
Health \* \* \*

"For the best results \* \* \* drink 2  
glasses on rising, 2 more during the morn-  
ing, 2 during the afternoon and 1 or 2  
at night \* \* \*"

The foregoing statements are said to be false and misleading because they represent that the article when consumed according to directions will rebuild the body while cleansing it of waste matter, will exert an alkaline effect on the body by counteracting acid condition, will serve to restore improperly functioning kidneys and bowels to their normal activity, and will exert benefits to health greatly in excess of those derived from the consumption of ordinary drinking water.



## [Suit Under 1906 Act]

In the former suit by the United States brought in the District Court for the Eastern District of Pennsylvania in 1928 "Capon Springs Water" was alleged to have been misbranded and was sought to be forfeited under the then terms of the Food and Drugs Act, which at that time required as a condition of any misbranding which would cause forfeiture of the articles therefor that the packages or labels containing them should bear a statement regarding the curative or therapeutic effects of the article "which is false and fraudulent." 21 U. S. C. § 10. But under the amended Food and Drug Act, 21 U. S. C. § 352, which governs the present litigation, a drug or device is deemed misbranded "(a) if its labeling is false or misleading in any particular." In other words, the amended act dispenses with the necessity of proving fraud in the misbranding so that the prior adjudication in *United States v. 94 Dozen, More or Less, Bottles Capon Springs Water*, 48 F. 2d 378, aff'd 51 F. 2d 913 (C. C. A. 3), to the effect that there was no fraud in the branding was not a bar to the present proceeding, since the court was not there required to make any finding that the statements were misleading if no fraud was proved and it made none. As the causes of action in that proceeding and in this are not the same, there is no *res judicata* and, as none of the present issues were determined in the prior proceeding, there is no estoppel.

## [Proceedings Before Federal Trade Commission]

In 1936 the Federal Trade Commission filed a complaint against Capon Water Company and Louis L. Austin, claimants herein, charging them with falsely advertising "Capon Springs Water" as curing or aiding in the treatment of many diseases and introduced as evidence of misbranding the label from which we have quoted beginning with the words: "Rebuilds as it cleanses \* \* \*" The Commission by its findings of January 20, 1938, determined that the claimants represented in their advertising that "Capon Springs Water" *alone* would cure the various diseases and ailments mentioned, whereas in fact the use of that water *alone* would not have such an effect, and the acts of the claimants therefore had a tendency to and did "mislead and deceive the purchasing public and caused them erroneously to believe that the use of said water alone will cure the various

diseases \* \* \*" The Commission accordingly ordered the Capon Water Company, Capon Springs Mineral Water, Inc., and Louis L. Austin to cease and desist from representing that the use of the water alone would cure the various diseases mentioned. The court below treated this order as equivalent to an approval of forms of advertising which did not represent that "Capon Spring Water" *alone* would cure or relieve the ills referred to. The Court's interpretation of the prior order is unwarranted. We cannot understand how a failure to make any finding except that the use of "Capon Springs Water" *alone* would not have curative effects can be the equivalent of a finding that the water had the curative effects when not used alone. For this reason there was no estoppel against the United States in the assertion of its general claims in the present libel. Clearly the decision in the prior proceeding was not *res judicata* since it was founded upon a different claim from that asserted in the case at bar. There can be no basis for the contention that the finding of the Commission that the claimants falsely represented that the use of "Capon Springs Water" *alone* would cure diseases should indirectly operate in their favor though they are the very parties against whom the former decision was rendered. Even if the decision had any relevance here it should operate as an estoppel against the claimants *pro tanto* rather than in their favor. Under any possible theory the former decision of the Commission that the representation was misleading that the use of "Capon Springs Water" *alone* would cure the various diseases, was a finding of an ultimate fact which under *The Evergreens v. Nunan*, 141 F. 2d 927 (C. C. A. 2) could not be used as a "*mediate datum*" in the present proceeding.

## [No Estoppel by Judgment Here]

In *George H. Lee Co. v. Federal Trade Commission*, 113 F. 2d 583 (C. C. A. 8), and *United States v. Willard Tablet Co.*, 141 F. 2d 141 (C. C. A. 7), it was held that an estoppel by judgment existed against the United States and the Federal Trade Commission in respect to findings of fact rendered in a prior proceeding which were in favor of the defendant. But in the case at bar no findings in favor of the claimants were made in the prior proceeding. They are here attempting to use the findings formerly rendered in favor of the United States for their benefit. The reason for such a contention we cannot comprehend.



*U. S. v. Phelps Dodge Mercantile Co.*

[*Remedies Are Cumulative*]

It is unnecessary for us to discuss here the contention of the plaintiff that, irrespective of any general rules of *res judicata* or estoppel by judgment, the Commission had a right to change its decision, for we have shown above that no such rules could be applicable under the facts disclosed in the record.

The suggestion of the claimants that because under § 45(1) of the Federal Trade

Commission Act they are made subject to a penalty for a violation of a cease and desist order, that remedy is exclusive and a forfeiture proceeding under the Food, Drug, and Cosmetic Act will not lie, is unwarranted. The remedies are plainly cumulative and not exclusive.

The order is reversed and the cause is remanded with directions to proceed in accordance with the views expressed in this opinion.

---

**UNITED STATES v. PHELPS DODGE MERCANTILE COMPANY**

United States Circuit Court of Appeals for the Ninth Circuit. No. 11249.

September 25, 1946. 157 F. 2d 453.

Certiorari denied, 330 U. S. 818 (1947).

The case involved seizure proceedings against a food product which had become adulterated while held in original packages in a warehouse at the termination of its interstate journey. The fact that the food was adulterated while held in original packages did not show that it was adulterated when introduced into or while in interstate commerce.

Sections 201 (b), 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The terms "interstate commerce" and "original packages" are not synonymous.

Sections 201 (b), 304 (a), Federal Food, Drug, and Cosmetic Act.

The provision of Section 10 of the Food and Drugs Act of 1906 with respect to original packages is not to be read into Section 304 (a) of the Federal Food, Drug, and Cosmetic Act by construction.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The administrative interpretation of Section 304 (a) of the Act to the effect that it provides for the condemnation of food that is adulterated while held in original packages after transportation in interstate commerce is clearly erroneous, and should not and need not be followed by the courts.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Theron L. Caudle, Assistant Attorney General, Washington, D. C., F. E. Flynn, U. S. Attorney, John P. Dougherty, Assistant U. S. Attorney, Phoenix, Ariz. (Vincent A. Kleinfeld, Attorney, Dept. of Justice, Arthur A. Dickerman, Attorney, Federal Security Agency, Washington, D. C., of counsel), for appellant.

Knapp, Boyle, Bilby, & Thompson, Arthur Henderson, Tuscon, Ariz., for appellee.

Before MATTHEWS, HEALY and BONE, Circuit Judges.

[*Nature of Proceedings*]

MATTHEWS, Circuit Judge: On an amended libel of information filed on September 28, 1945, appellant, the United States, proceeded against 175 cartons of food (150 cartons of spaghetti and 25 cartons of macaroni) in possession of appellee, Phelps Dodge Mercantile Company, in the District of Arizona. The amended libel, hereafter called the libel, prayed that the food be seized and

condemned. The food was seized. Appellee excepted to the sufficiency of the libel. The exception was sustained, and a decree was entered dismissing the libel and directing that the food be released to appellee. From that decree this appeal is prosecuted. The question is whether the libel stated facts sufficient to warrant condemnation of the food.



*[Pertinent Section of Act]*

Condemnation was sought under § 304 (a) of the Federal Food, Drug and Cosmetic Act,<sup>1</sup> 21 U. S. C. A. § 334 (a), which provides:

"Any article of food \* \* \* that is adulterated<sup>2</sup> \* \* \* when introduced into or while in interstate commerce<sup>3</sup> \* \* \* shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found \* \* \*"

*[Allegations of Libel]*

The libel stated that the food was shipped in interstate commerce from Denver, Colorado, to Douglas, Arizona, in 1943—75 cartons on February 13, 1943, and 100 cartons on June 18, 1943. The libel further stated:

"That said food \* \* \* is [on September 28, 1945] adulterated within the meaning of 21 U. S. C. A. as follows:

"342(a)(3) in that it consists wholly or in part of a filthy substance<sup>4</sup> by reason of the presence therein of insect fragments, rodent hairs, and rodent excreta;

"342(a)(4) in that it has been held under unsanitary conditions whereby it has been contaminated with filth<sup>5</sup> while held in the original packages by [appellee] at [appellee's] warehouse in Douglas, Arizona."

Thus, the libel stated, in substance and effect, that on September 28, 1945—more than two years after it was shipped in interstate commerce—the food was adulterated. The libel did not state that the food was adulterated when introduced into or while in interstate commerce.<sup>6</sup> Instead, the libel

stated, in substance and effect, that the food was adulterated while held in original packages by appellee at its warehouse in Douglas, Arizona. Thus it appeared that the adulteration of the food occurred after it ended its interstate journey and came to rest at appellee's warehouse.<sup>7</sup>

*[Contention of Appellant]*

Appellant contends that the fact that the food was adulterated while held in original packages was sufficient to warrant its condemnation. We do not agree. As shown above, § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a), under which this proceeding was brought, provides for the condemnation of "Any article of food \* \* \* that is adulterated \* \* \* when introduced into or while in interstate commerce." It says nothing about original packages. The terms "interstate commerce" and "original packages" are not synonymous. Articles may be in interstate commerce without being in original packages. They may be in original packages without being in interstate commerce. They may be in both interstate commerce and original packages and, if in both, may cease to be in interstate commerce and yet remain in original packages.<sup>8</sup> Hence the fact that the food was adulterated while held in original packages did not show that it was adulterated when introduced into or while in interstate commerce.

*[Food and Drug Act of 1906 Not Applicable]*

Appellant cites, in support of its contention, § 10 of the Food and Drug Act of 1906,<sup>9</sup> 21 U. S. C. A. § 14, which provided that "any article of food \* \* \* that is adul-

<sup>1</sup> Act of June 25, 1938, c. 675, 52 Stat. 1040, as amended.

<sup>2</sup> Section 402 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 342, provides: "A food shall be deemed to be adulterated.

"(a) \* \* \* (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance \* \* \* or (4) if this has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth \* \* \*"

<sup>3</sup> Section 201 (b) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 321(b), provides: "The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof, and commerce within the District of Columbia or within any other Territory not organized with a legislative body."

<sup>4</sup> See § 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 342(a)(3).

<sup>5</sup> See § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 342(a)(4).

<sup>6</sup> See § 304(a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334(a).

<sup>7</sup> Cf. *American Steel & Wire Co. v. Speed*, 192 U. S. 500; *General Oil Co. v. Crain*, 209 U. S. 211; *Bacon v. Illinois*, 227 U. S. 504; *Texas Co. v. Brown*, 258 U. S. 466; *Sonneborn v. Cureton*, 262 U. S. 506; *Gregg Dyeing Co. v. Query*, 286 U. S. 472; *Nashville, C. & St. L. R. Co. v. Wallace*, 288 U. S. 249; *Louis K. Liggett Co. v. Lee*, 288 U. S. 517; *Edelman v. Boeing Air Transport*, 289 U. S. 249; *Southern Pac. Co. v. Gallagher*, 306 U. S. 167; *Walling v. Jacksonville Paper Co.*, 317 U. S. 564; *Higgins v. Carr Bros. Co.*, 317 U. S. 572.

<sup>8</sup> Cf. *Woodruff v. Parham*, 8 Wall. 123; *Hinson v. Lott*, 8 Wall. 148; *American Steel & Wire Co. v. Speed*, *supra*; *Baccus v. Louisiana*, 232 U. S. 334; *Wagner v. Covington*, 251 U. S. 95; *Sonneborn v. Cureton*, *supra*; *Wilcoil Corp. v. Pennsylvania*, 294 U. S. 169; *Whitfield v. Ohio*, 297 U. S. 431.

<sup>9</sup> Act of June 30, 1906, c. 3915, 34 Stat. 768, as amended.



*U. S. v. 3 Unlabeled 25-Pound Bags Dried Mushrooms*

terated \* \* \* and is being transported from one State \* \* \* to another for sale, or having been transported, remains \* \* \* in original unbroken packages \* \* \* shall be liable to be proceeded against \* \* \* and seized for confiscation by a process of libel for condemnation." This proceeding was not brought, and could not have been brought, under § 10 of the Food and Drug Act of 1906, 21 U. S. C. A. § 14, for that section was repealed<sup>10</sup> long before this proceeding was brought. As stated above, this proceeding was brought under § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a). The quoted provision of § 10 of the Food and Drug Act of 1906, 21 U. S. C. A. § 14, is not in § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a), and should not be read into it by construction.

Whether Congress could have provided in § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a), for the condemnation of any article of food that

is adulterated while held in original packages after being transported in interstate commerce need not be considered, since Congress did not, in fact, so provide.

*[Administrative Interpretation]*

Appellant says that administrative officers charged with the duty of enforcing § 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334 (a), have interpreted it as providing for the condemnation of any article of food that is adulterated while held in original packages after being transported in interstate commerce. Being clearly erroneous, that interpretation need not and should not be followed by the courts.<sup>11</sup>

Appellant has cited no court decision supporting its contention, and we have found none. We conclude, as did the court below, that the libel did not state facts sufficient to warrant condemnation of the food.

Decree affirmed.

**UNITED STATES v. 3 UNLABELED 25-POUND BAGS,  
MORE OR LESS, 2 UNLABELED 25-POUND BOXES,  
MORE OR LESS, DRIED MUSHROOMS**

United States Circuit Court of Appeals for the Seventh Circuit. No. 8988.  
October 17, 1946. 157 F. 2d 722.

The case involved seizure proceedings against mushrooms alleged to be adulterated. After trial, a decree of condemnation was entered. An appeal was taken, but since no stay of the decree had been obtained, the marshal destroyed the mushrooms. The continued existence of the product was essential to the right of the circuit court of appeals to proceed against the things themselves, since the goods are the party defendant in such a proceeding.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The decree of condemnation of the district court went against the mushrooms, and the decree having been entered and executed, the proceeding was *functus officio*.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Where the product proceeded against in a seizure action under the Act is destroyed, the cause is rendered moot and the circuit court of appeals cannot entertain an appeal, since the court is not authorized to decide arguments but only "cases and controversies."

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

<sup>10</sup> See § 902(a) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1059, and notes appended to 21 U. S. C. A. §§ 14 and 392.

<sup>11</sup> Cf. *United States v. Tanner*, 147 U. S. 661; *United States v. Missouri Pac. R. Co.*, 278 U. S. 269; *Texas & Pac. R. Co. v. United States*, 289

U. S. 627; *Koshland v. Helvering*, 298 U. S. 441; *Estate of Sanford v. Commissioner*, 308 U. S. 39; *Neuberger v. Commissioner*, 311 U. S. 83; *Interstate Commerce Commission v. Railway Labor Executives Ass'n.*, 315 U. S. 373; *Jewell Ridge Coal Corp. v. Local No. 6167*, 325 U. S. 161.



Federal Food, Drug, and Cosmetic Act  
*U. S. v. 3 Unlabeled 25-Pound Bags Dried Mushrooms*

Benjamin F. Morrison, for appellant.

J. Albert Woll, U. S. Atty., John M. Kiely and M. C. Handleman, Asst. U. S. Attys., Theron L. Caudle, Asst. Atty. Gen. (Vincent A. Kleinfeld, Atty., Department of Justice, of counsel), for appellee.

Before SPARKS and MINTON, Circuit Judges, and BRIGGLE, District Judge.

[*Nature of Proceedings*]

MINTON, Circuit Judge: The United States filed a libel against three bags and two boxes of mushrooms shipped in interstate commerce, claiming they were adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.<sup>1</sup> One H. Beitch, doing business as the Russian-Polish Importing Company, appeared as claimant and answered, taking issue among other things with the allegation that the mushrooms were adulterated. A trial was had before the court. The court found the mushrooms were adulterated within the meaning of the Act, and on July 13, 1945 entered a decree that the mushrooms be condemned, forfeited, and destroyed.

[*No Stay of Court's Action Entered*]

The claimant filed a motion to vacate this judgment and for a new trial. This motion was overruled on the 11th day of October, 1945, at which time the claimant gave notice of appeal. In the meantime, no stay of the court's order or decree having been entered, the Marshal destroyed the mushrooms. Therefore, the subject matter of the libel and of this action is no longer in existence.

The continued existence of the mushrooms is essential to our right to proceed against the things themselves. The action is an action *in rem*. In such a proceeding, there is no party defendant. The goods stand to answer. They are the offenders. *Day v. Micou*, 85 U. S. 156, 162, 21 L. Ed.

860; *National Bond & Investment Co. v. Gibson*, 6 F. 2d 288, 290.

The decree of the District Court goes against the mushrooms. The decree having been entered and executed, the proceeding is *functus officio*.

[*Court Will Not Decide Moot Questions*]

Counsel for the Government readily admits the matter is moot here and counsel for the claimant reluctantly admits it is moot, but both parties ask us to decide the issue between them. This we decline to do. If we were to affirm the judgment, the District Court could not destroy the mushrooms. They have already been destroyed. If we reversed the judgment, there would be no mushrooms to restore to the claimant. The cause is clearly moot. We are not authorized to decide arguments but only "cases and controversies." 14 Am. Jur., Courts, § 49.

In a cause where the facts were identical with those in this cause, except that they arose under the Tariff Act instead of the Federal Food, Drug, and Cosmetic Act, the appeal was dismissed. See *Eureka Productions, Inc. v. Mulligan*, 108 F. 2d 760. From an early date it has been held that in forfeiture proceedings such as this, the continued existence of the articles is essential. *United States v. Ninety-two Barrels of Rectified Spirits*, Fed. Cases 15,892, 8 Blatchford 480 (1871).

The appeal is

DISMISSED.

---

<sup>1</sup> 21 U. S. C. A. § 301 *et seq.*, 52 Stat. 1040 *et seq.*



UNITED STATES v. CATALDO

United States Circuit Court of Appeals for the First Circuit. No. 4173.  
October 31, 1946. 157 F. 2d 802.

The case involved seizure proceedings against candy alleged to be misbranded under Section 403 (d) of the Act in that its container was so filled as to be misleading, since the boxes in which the candy was packed could hold approximately 50 per cent more candy. The candy occupied 45.3 per cent of the volume of the carton in which the smaller units containing the individual pieces of candy were placed. There is no hard and fast rule as to what constitutes slack-filling, and whether or not over 50 per cent space in a package constitutes slack-filling was a question of fact for the district court to decide.

Sections 304 (a), 403 (d), Federal Food, Drug, and Cosmetic Act.

Whether or not the articles were "palmed off" on the public, or whether or not the markings on the package were proper, were questions not relevant to the issue of slack-filling in the case.

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

The district court would not be reversed since, although it had referred to "palming-off" and label marking, it nevertheless had held that there was no testimony that the boxes could hold approximately 50 per cent more candy and that it was not convinced that the wrapping and size were misleading.

Sections 304 (a), 403 (d), Federal Food, Drug, and Cosmetic Act.

The Federal Rules of Civil Procedure govern appeals in actions for the forfeiture of property for violation of a statute of the United States; under Rule 52 (a) findings of fact may not be set aside unless clearly erroneous; and the circuit court of appeals could not say that the finding of the district court that the container was not so made, formed, or filled as to be misleading was clearly erroneous.

Sections 304 (a), 304 (b), 403 (d), Federal Food, Drug, and Cosmetic Act.

Vincent A. Kleinfeld, Attorney, Department of Justice, with whom Theron L. Caudle, Assistant Attorney General, George F. Troy, U. S. Attorney, Joseph L. Breen, Assistant U. S. Attorney, and James B. Goding, Attorney, Federal Security Agency, were on the brief, for appellant.

Michael Carchia, with whom Charles B. Garbedian was on the brief, for appellee.  
Before MAHONEY, GOODRICH and WOODBURY, Circuit Judges.

[*Nature of Proceedings*]

MAHONEY, Circuit Judge: This is an appeal from the dismissal of a libel brought under the Federal Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040 (1938), 21 U. S. C. 301 *et seq.* (1940)), for the condemnation of certain articles of food consisting of 193 cartons, more or less, each containing eighteen boxes of a food labeled in part: "Benevento Brand Nougat Net Weight 9 Ounces Contains 18 Pieces Weighing ½ Ounce Each, Consisting of Sugar, Honey, Almonds, Egg Whites, Cinnamon, Wafer \* \* \*", which were shipped in interstate

commerce from Boston to Providence. The libel charged misbranding within the meaning of § 403 (d)<sup>1</sup> of the Act in that its container is so filled as to be misleading since the boxes could hold approximately 50 per cent more candy.

[*Answer of Claimant*]

In his answer the claimant sought the return of the articles alleging that he was the owner of the Liberty Chocolate Company which shipped the articles from Boston to Providence in interstate commerce and denied that they were misbranded and liable

<sup>1</sup> "Sec. 403(d). A food shall be deemed to be misbranded—if its container is so made, formed,

or filled as to be misleading." 21 U. S. C. § 343(d) (1940).



to seizure and condemnation. He averred that he had manufactured and packaged the articles under his individual name for a long time and that the large carton measures approximately 6" x 8" and is 1½" deep and each carton contains eighteen small boxes; each small box measures 1¼" in width, 2" in length and about 1" in depth, and bears the same description and representation as the outer package; that each of these small boxes contains one piece of candy, one-half ounce in weight, known as "Torrone". Each piece is wrapped with a piece of wafer and measures approximately 1" in width, 1⅞" in length and ½" in depth. These boxes and cartons are similar in size, description and contents to those of other manufacturers in the trade. He denied that they were misbranded and prayed for a dismissal of the libel.

[*Question at Issue*]

The question is whether the containers of the article were so made, formed or filled as to be misleading thereby constituting misbranding within the meaning of § 403 (d) of the Act.

[*Contention of Government*]

The libelant contends that the libelee has violated the provisions of § 403 (d) of the Act by shipping in interstate commerce packages of food, in this instance candy, which are slack-filled, that is, in containers only partly filled with candy and partly filled with wrapping and is so prepared that it would be a source of deception to the public. It contends that the containers are less than 50 per cent filled with candy and refers to the Congressional history of the Act to demonstrate that slack-filling was one of the things that Congress meant to prohibit for the protection of the public.

There was produced in evidence for the libelant one of six large containers which had been taken from the 193 cartons originally shipped in interstate commerce and marked "Exhibit 1". A witness for the libelant testified that the large cartons were flat and rectangular in shape, with flaps at both ends, and that they contained eighteen small cartons which completely filled the larger one. From each of three large cartons there were taken five small units containing candy. The candy was unwrapped and it was determined that the average dimension per piece of candy was 1.05 cubic inches. The internal volume of the small cartons was determined to be 2.32 cubic inches. The candy occupied 45.3 per

cent of the entire volume of the carton. He also testified that it was due to bulky wrapping that the candy appeared to fill the package adequately but he said that if the wrapped candy were pressed tightly against the side of the carton a considerable amount of space became apparent and if the wrapped candy were pressed toward the end of the box a considerable end space also became evident. He also said that when the paper was removed and the candy placed back in the box it was pretty loose. Certain small containers were handed to the judge and the witness demonstrated what his report meant.

[*No Rule for Slack-Filling*]

There is no hard and fast rule as to what would constitute slack-filling. Whether or not over 50 per cent space in a particular package of candy was slack-filling is a question of fact for the district court to decide. It had before it samples of the containers, both large and small; it examined them and commented on the fact that apparently there was a very slight space in the package.

[*Evidence in Lower Court*]

In making its decision the court referred to the fact that there was no evidence before it that containers of the type of Exhibit 1 had been "palmed off" on the public, and also that there was no testimony on behalf of the libelant that the markings would be misleading or would likely be misleading to an average purchaser, and seemed to rely upon the fact that proof of actual deception in the sale of the candy was necessary, citing *United States v. 2 Bags, etc., of Poppy Seeds*, 54 F. Supp. 706 (N. D. E. D. Ohio, 1944). However this case had been overruled by the Circuit Court of Appeals, *United States v. 2 Bags, etc., of Poppy Seeds*, 147 F. (2d) 123 (C. C. A. 6th, 1945). Whether or not the articles in question had been "palmed off" on the public or whether or not the markings on the package were proper markings were questions not relevant to the issue in this case which the district court was called upon to consider.

Although the trial court did refer to these conditions which are covered by other sections of the Act, it nevertheless held that there was no testimony to the effect that the boxes could hold approximately 50 per cent more candy, and was not convinced by the testimony that the wrappings and size were misleading. It stated that it would be "stretching the statute all out of proportion



to its purpose if it were to find on the evidence in this case, dealing with this particular nougat, the way it is shaped and wrapped, that that container was so made, formed and filled as to be misleading", and that there was nothing "in the shape and size of the larger package or the smaller packages that would be misleading to a person". Moreover, the court held that it could not as a matter of law say either that the product has been misbranded or that its "containers are so made, formed or filled as to be misleading."

[*Federal Rules of Civil Procedure Govern*]

The Federal Rules of Civil Procedure govern proceedings on appeals in actions for the forfeiture of property for violation of a statute of the United States. Rule 81(a) (2). This case is an action under the Federal Food, Drug, and Cosmetic Act of 1938, which is a statute of the United States and is on appeal before us. Under Rule 52 (a) of said Rules, findings of fact shall not be set aside unless clearly erroneous. We cannot say the finding that the container was not so made, formed or filled as to be misleading is clearly erroneous.

*The decree of the District Court is affirmed.*

## UNITED STATES v. 1322 CANS, MORE OR LESS, OF BLACK RASPBERRY PUREE

United States District Court for the Northern District of Ohio, Eastern Division. No. 23741 Civil. November 6, 1946. 68 F. Supp. 881.

In a seizure action against food alleged to be adulterated, a consent decree of condemnation was entered which allowed the reconditioning of the product by distillation or reprocessing for making cordials, etc., subject to the approval of the Food and Drug Administration. The Administration refused to supervise a reconditioning process of the filtration type because of its view that such process would not produce a product it would approve for human consumption. After a product has been condemned, its reprocess is a permissive matter within the discretion of the court.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

Where several methods of reprocessing are enumerated in a decree, the question of who shall determine the one to be used, and which will bring the reconditioned product into compliance with the Act, is for the determination of the Food and Drug Administration.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

There was no abuse of discretion in the determination of the Food and Drug Administration that distillation of the condemned article was the only process which would recondition the product for human consumption, and the court could not interfere with such determination.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Don C. Miller, U. S. Attorney, Cleveland, Ohio, for plaintiff.  
Don Wick, Cleveland, Ohio, for defendant.

[*Consent Decree for Condemnation*]

JONES, District Judge: This case was disposed of by a consent decree approved by attorneys for the claimant and the United States Attorney representing the Government. The decree provides for the condemnation of the black raspberry puree because it was adulterated and upon bond allows the reconditioning by distillation or reprocessing for making cordials, brandies or jellies but subject to the approval of the Food and

Drug Administration of the Federal Security Agency.

[*Conflict as to Method of Reprocessing*]

The claimant wants to reprocess the puree by filtration and make jelly of it. The Food and Drug Administration objects to this method and refuses to supervise a reconditioning process of the filtration type because, as it says, such a process would not produce a product which it would approve for human consumption.



The claimant has filed a motion for an order of the court to require the Food and Drug Administration to supervise such a reprocessing. The plaintiff has moved to set aside that portion of the decree which allows the reprocessing by the pressing or filtration method. Voluminous briefs and affidavits have been filed by both parties.

There is some doubt as to the authority of the court to alter a consent decree. However, it seems unnecessary to change the decree of the court. Without a trial it is not possible to determine whether the reprocessing method proposed by the claimant complies with the provisions of the Pure Food and Drug Law. That was not an issue in this case nor should it be determined on the motion of the claimant supported by affidavits and the briefs filed. That would be the issue in a new case if the claimant were allowed to reprocess the puree as it proposes and if the puree were subsequently condemned by the Food and Drug Administration.

*[Food and Drug Administration Must Supervise Reprocessing]*

The purpose of vesting discretion and supervisory powers in the Food and Drug Administration as to reprocessing was to avoid such a succession of suits. After a product has been condemned its reprocess is a permissive matter within the discretion of the court as indicated by the use of the word "may" in the statute. The statute also provides that the reconditioned puree must be brought into compliance with the provisions of the Pure Food and Drug law under the supervision of the Administration. Where several methods of reprocessing are enumerated, as in this decree, the question of

who shall determine the one to be used and which, when used, will bring the reconditioned puree into compliance with the statute seems to be the only question for decision, i.e., does the claimant who does the reprocessing or the Food and Drug Administration under whose supervision the work is to be done have the right to determine the method which would bring the reprocessed product into compliance with the law?

The Food and Drug Administration has determined that distillation is the only process which would recondition this puree for human consumption and which it would approve. I see no abuse of discretion in making this determination nor can the court interfere with that determination. To interfere would be substituting the judgment of the court for that of the Food and Drug Administration upon a matter which it is better able to decide and upon an issue which I think is not properly joined in this case.

*[Financial Loss to Claimant Immaterial]*

The fact that the claimant will suffer financial loss is not of great materiality. Its product was found to be unfit for human consumption and the reconditioning is not a matter of right but of permission by the court.

The motion of the claimant will be denied.

The motion of the Government insofar as it seeks to alter the decree will likewise be denied.

An entry may be presented in accordance with this ruling.



*U. S. v. Six Dozen Bottles "Dr. Peter's Kuriko"*

**UNITED STATES v. SIX DOZEN BOTTLES, MORE OR LESS, OF "DR. PETER'S KURIKO"**

United States Circuit Court of Appeals for the Seventh Circuit. No. 9047.

January 2, 1947. 158 F. 2d 667.

In a seizure action against a drug product alleged to be misbranded because of false and misleading therapeutic claims, statements contained in a pamphlet wrapped around each bottle of the product could be held to be misleading when the pamphlet was considered in its entirety, even though the statements were not literally false.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The statement that the product would give relief from functional constipation and certain ailments due to constipation was not misleading, but the court could not say the jury was not justified in inferring that another statement, that the product "fights functional constipation," was misleading because it conveyed the impression that it was a remedy or cure for constipation rather than a mere relief.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

A page of the pamphlet setting forth in large black type the names of various ailments, with a picture of a person shown to be in distress, furnished the basis for a finding that the representations were misleading, considering the form of the arrangement, the pictures, and the ailments specified, notwithstanding the fact that the page stated, in fine print, that the product would bring relief only when the ailment was caused by constipation.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Proof of any one of the charges contained in a libel of information is sufficient to justify a decree of condemnation.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Since the libel of information did not contain a charge that the product was misbranded because its labeling did not bear adequate directions for use, the question should not have been submitted to the jury; but the error was not prejudicial, since the jury's answer to the question did not detract from its answer to another proper question and bore no relation to the latter answer.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The weighing of testimony is not a function of a circuit court of appeals but of the jury.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Before MAJOR, KERNER, and MINTON, Circuit Judges.

*[Nature of Proceeding]*

MAJOR, Circuit Judge: This is an appeal from a decree entered January 22, 1946, in a proceeding commenced by the filing of a Libel Information under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301 *et seq.*, which prayed the condemnation of an article called Dr. Peter's Kuriko, on the ground that it was misbranded when in interstate commerce. The *res* involved is a medicine manufactured by Dr. Peter Fahrney & Sons Company, referred to as the claimant which intervened and defended the action. The cause was tried to a jury and

a special verdict was returned which constitutes the basis for the decree in controversy.

The libel as filed charged misbranding in a number of ways, all of which charges have been eliminated in one way or another except that contained in paragraph IIIa, which alleged that the article was misbranded within the meaning of 21 U. S. C. A. 352 (a) in that certain representations in the labeling were false and misleading since the product, when taken as directed, will not fulfill the promises of benefit stated and implied therein.



*[Verdict of the Jury]*

The special verdict of the jury, on questions framed by the court, was as follows:

"1. Is the labeling of Kuriko false or misleading in that the product, when taken as directed, will not fulfill the promises of benefit, stated or implied?

"Answer: Yes.

"2. Does the labeling of Kuriko, including the directions thereon, provide for the continuous use of Kuriko?

"Answer: No.

"3. If you answer Question 2 'Yes,' then answer this question. Is the continuous use of Kuriko capable of causing a dependency upon laxatives to move the bowels?

"Answer:

"4. Is Kuriko misbranded in that the labeling fails to bear adequate directions for use in any respect?

"Answer: Yes."

*[Issue Raised]*

The primary issue raised before this court arises from the contention that there was no substantial evidence which would justify the submission of the case to the jury and that there should have been a directed verdict in favor of the claimant. It is also contended that the submission to the jury of question 4 was prejudicial error because there was no charge in the libel to which it was responsive. In connection with this contention, it is also asserted that the court improperly admitted the opinion testimony of a witness who was not qualified.

Kuriko is a medicine which has long been manufactured and sold to the public. Admittedly, it is a laxative and relieves functional constipation. That is the limit, however, of its remedial qualities. In fact, we do not understand that anything further is claimed for it. Notwithstanding this, claimant in a pamphlet wrapped around each bottle of its product devoted four pages extolling benefits to be derived from its use. We think no good purpose could be served in setting forth the contents of this pamphlet. It is sufficient to state that we have studied it and we are of the view that the representations contained therein were such as to present a proper question for the jury as to whether they were misleading. It may be, as claimant insists, that there were no statements contained in the pamphlet which were literally false, but even so it does not follow that it was not misleading when considered in its entirety.

*[Representations]*

We shall mention only a few of the statements contained in this pamphlet, from which we think a jury might have reasonably inferred that the product was represented either as a remedy or a cure for something other than constipation. On the first page, under the heading in large black type, "What it is," appears the following in small type, "The family medicine of 5 generations designed for relief from functional constipation and, when these troubles are due to constipation, for relief from nervousness, indigestion, upset stomach, headaches, loss of sleep and appetite, flatulence, foul breath and coated tongue." In other words, by this statement the reader is informed that the remedy is only a relief from the ailments mentioned when they are due to constipation. It appears there could be nothing misleading in this statement. On the same page, however, under another heading in large black type, "What it does," is the following statement, also in heavy type, "Kuriko fights functional constipation." The government contends that the buying public may infer from this statement that it is a remedy or cure for constipation rather than a mere relief. We are not greatly impressed with the government's contention in this respect but this representation, as others, was submitted to the jury and we cannot say that the jury was not justified in inferring that the statement was misleading.

In our judgment, the more important statements in the pamphlet calculated to mislead are found on the second page, printed in large black type. "Here's what may happen when you are constipated," followed by five paragraphs, entitled "Functional constipation," "Nervousness," "Flatulence," "Headaches," and "Common colds." The title of each paragraph is also in heavy black type, and opposite each is a picture of a person shown to be in misery and distress. It is true that the fine print in each of these paragraphs gives the information that Kuriko will bring relief only when the ailment is caused by constipation. We are of the view, however, that this page of the pamphlet alone, considering the form of its arrangement, the ailments which are listed in large type and the limitation with reference thereto in small type, in connection with the pictures of persons evidently in misery and distress, furnishes the basis for a finding that the representations were misleading.



*[Medical Testimony]*

A great deal of medical testimony was offered by both sides which it is argued supports the contentions of the respective parties. Again we think no useful purpose could be served in an attempt to analyze or dissect this expert testimony as it pertains to the issues in controversy. In fact, to do so would involve a weighing of the testimony, which is not our function but was that of the jury. The only contention made here which might be regarded as serious is that which arises from the submission to the jury of question 4, and its finding that Kuriko is misbranded because the labeling "fails to bear adequate directions for use in any respect." Concededly there was no charge in the information to which this question and answer was responsive. The only reason we find for its submission is a statement by the court that it desired an answer to the question for its own information. We are of the view that this question should not have been submitted but, even so, we are also of the view that it was not prejudicial. As this court

has held, proof of any one of the claims contained in the information is sufficient. *United States v. Dr. Roberts Veterinary Co.*, 104 F. 2d 785, 789.

*[No Prejudicial Error]*

The jury's answer to this question neither adds nor detracts from its answer to the first question, which was responsive to the charge contained in paragraph IIIa. The answer to question 1 forms the basis for a decree and this irrespective of the answer to question 4. This would still be the situation if the jury's answer to question 4 had been "No." There is nothing to indicate and no reason to think that the jury's answer to question 4 bore any relation to its answer to question 1. In other words, as far as we are able to discern, the jury's answer to question 1 was not dependent in any manner or to any extent upon its answer to question 4. We therefore are of the view that the submission of question 4 could have had no prejudicial effect.

The decree is AFFIRMED.

**UNITED STATES v. ONE DEVICE, INTENDED FOR  
USE AS A COLONIC IRRIGATOR, BEARING A  
PLATE READING "TOX ELIMINATOR—  
TOX ELIMINATOR CO.," ETC.**

United States Circuit Court of Appeals for the Tenth Circuit.  
Nos. 3374-3375. February 27, 1947. 160 F. 2d 194.

In seizure proceedings against a device alleged to be misbranded because of false and misleading therapeutic claims, the weight of authority is that medical books and treatises are not admissible to prove the statements therein contained.

Sections 201 (h), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Medical experts who were familiar with the principles of the device, a colonic irrigator, and with colonic irrigation, were not disqualified merely because they had not used the device or seen it in operation.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Ordinarily an ultimate finding of fact by a trial court is binding upon the appellate court if sustained by the record, but if the finding is clearly erroneous or is based upon a misapplication of law to evidentiary findings, it is not binding upon the appellate court.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The Government's charge of misbranding would be established if the evidence proved any one of the representations made on behalf of the device to be false; and the Government established the falsity of many of the representatives.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.



Circulars pertaining to the product were intended to induce the belief that the device promised absolute relief from various ailments, and were inherently dishonest and deceiving.

Sections 201 (m), 502 (a), Federal Food, Drug, and Cosmetic Act.

Deception may result from the use of statements not technically false or which may be literally true. It is not difficult to choose statements, designs, and devices which will not deceive.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Scott M. Matheson (Theron L. Caudle, Dan B. Shields, U. S. Attorney, Oliver K. Clay, John T. Grigsby and Lawrence E. Bobker were with him on the brief), for appellant.

David H. Cannon (Reed E. McCallister with him on the brief), for appellee.

Before PHILLIPS, BRATTON and HUXMAN, Circuit Judges.

HUXMAN, Circuit Judge: The government has appealed from the judgment of the United States District Court for the District of Utah denying its prayer for the seizure and condemnation of two certain devices, each bearing a plate reading "Tox-Eliminator Tox Eliminator Co. Inc. Glendale, Calif. Ser. No. 513," and for the seizure of certain circulars which accompanied the devices. The devices are identical, differing only as to the number of the name plate attached thereto. The action was instituted under the Federal Food and Drug Act, 21 U. S. C. A. 301 et seq.<sup>1</sup> Trial was to the court, and judgment was entered dismissing the libel.

[Facts]

The parties stipulated that the sale of the two devices in question had been made, one to a doctor of naturopathy and the other to a doctor of chiropractic, and that the devices were displayed in the places of business of these two men for the purpose of selling the service of the devices, and that

the devices were displayed together with certain circulars extolling their merits, and that both the device and the circulars had been transported in interstate commerce.

The device is described as a colonic irrigator. It differs from an ordinary enema device in that it has an inflow and an outflow tube. The inflow tube is equipped with a thermostatic valve by which the temperature of the water can be regulated, and a pressure valve which limits the pressure of the water entering the body to forty inches. The outflow tube has a transparent arrangement by which the contents coming from the bowels can be seen and observed as they leave the body. One of the circulars involved was labeled "The Modern Scientific Drugless Way to Health," and the other was called "The Magic Power of Water."<sup>2</sup> The device is attached to an ordinary water faucet while in use, and uses water coming from water mains. Much of the controversy centers around the representations contained in these two circulars.

<sup>1</sup> The applicable statutes are as follows:

321 "(h) the term 'device' . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

321 "(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

"Sec. 352. Misbranding drugs and devices.

"A drug or device shall be deemed to be misbranded . . .

"False or misleading label

"(a) If its labeling is false or misleading in any particular."

<sup>2</sup> These two circulars in part read as follows:

"The Magic Power of Water

"From 58 to 65 per cent of the human body is water.

"The bones have only 22 per cent, but the liver contains 69 per cent, muscles 75 per cent,

and the kidneys as much as 82 per cent.

"The inside of the cells is fluid and consists largely of a solution of various substances in water. Bodily activity depends on aqueous solutions. Water is used to flush away the waste products of cell activity."

"Water furnishes a medium for digestion, absorption, metabolism (chemical change within the body in nutrition and secretion), and excretion. All these processes, chemical or physical, can take place only in the presence of water. Water is the vehicle for transportation of food, waste, hormones (internal secretions), gases, etc.

"Water is taken into the body not only with our drink but with nearly all foods; fresh meat and vegetables average about 75 per cent of water. It is absorbed mainly from the small intestine.

"By means of the lungs, skin and kidneys we eliminate water. There is a tube, leading out of each kidney, down which there runs a continual trickle of water, carrying dissolved in it the waste substances which have been separated from the blood.

(Footnote 2 is continued on page 201.)



*[Government's Case Based Upon Testimony of Medical Experts]*

The government's case was based upon the testimony of five medical experts whose qualifications in their respective fields stand admitted. They testified that while they had never used the device or had never seen it in use, they understood fully the principles upon which it operated, namely, the washing out of the colon by forcing a

"Air contains oxygen which enters the blood stream through the lungs and revitalizes it. A pure blood stream is a prime essential to health. By means of water and air poisonous waste matter is eliminated through the bowels, kidneys, lungs, skin and liver.

"Tox-Elimination is a new method of treatment for disturbed bowel conditions using Nature's agencies, water and air. It is astonishingly effective in a wide variety of cases where all other treatments have failed. Come and see for yourself what Nature's magic powers, properly employed, can do for you. If the examination shows your case to be one which requires the services of the Tox-Eliminator, a demonstration treatment will be given. If you are not entirely convinced, there will be no charge. . . .

*"10 Points of Tox-Elimination"*

"This natural and drugless therapy assists in accomplishing the following:

"1. Cleansing the colon, thoroughly and in a harmless manner.

"2. Massaging the bowel and helping give necessary tone to tissues involved.

"3. Helps to purify the blood stream; proved by microscopic examination after treatments.

"4. Assists in relieving rheumatic, arthritic and neuritic pain.

"5. Helps reduce hypertension or high blood pressure, thus easing the work of the heart and freeing its cells, and the brain, from undue strain.

"6. Helps to lessen the extra burden which is thrown on the liver and kidneys by improper elimination.

"7. Assists and improves sinus and antrum complications.

"8. Helps in re-establishing a normal peristalsis or natural muscular activity of the intestines.

"9. Helps improve the complexion, by assisting in eliminating the causes of pollution of the blood stream.

"10. Helps in preventing the hardening of the arteries, by minimizing the deposits of calcium and magnesium salts on arterial wall. . . .

"Tox-Elimination is a remarkable new treatment that cannot be compared with any other. I firmly believe this instrument will enable me to more thoroughly cleanse the colon of disease-producing waste than is possible by any other method.

"A pulsating stream of water and air bubbles is introduced into the bowel in a scientific-

stream of pulsating water into the intestines. They explained in considerable detail the physiology of the human system, as well as the causes of many of the diseases listed in the circulars, and the treatments therefor where known. They admitted that the causes of a number of the diseases of the body listed in these circulars were still unknown, and that the treatment therefor was not definitely catalogued. They testified that intestinal toxemia, referred to in

ally controlled manner. This pulsating stream penetrates readily into the impacted colon, hitherto inaccessible to most any other method of treatment. A sluggish or diseased colon is a contributing cause of most ailments.

"The air, oxygen and water loosen and dissolve the coats of mucus and stale encrusted fecal matter that adheres to the walls of the large bowel—in many instances causing it to become distended or ballooned.

"When the liver, colon and kidneys are not in perfect order they cannot do their work properly and as a result toxins are not properly discharged and are carried by the blood to every part of the body, tissues, joints, sinus, appendix, gall bladder and so on.

"Drugless methods, by removing the disease-producing materials at their foundation head, help the body to stop further damage and rebuild the affected parts and restore them to normal. Causes of irritation and numerous infections are removed. . . .

"The Modern, Scientific, Drugless Way to Health.

"My policy of keeping abreast of latest developments and providing my patients with the very best science has to offer in the treatment and relief of disease has made it necessary for me to adopt a remarkable new instrument to assist in getting at the very bottom and basic cause of a large number of ailments that have heretofore resisted the very best efforts of all branches of healing.

"When the colon is not functioning properly, the small intestine, stomach and the entire digestive tract are sure to be affected.

"I believe this new instrument, the Tox Eliminator, will enable me to more thoroughly cleanse the colon than is possible by any other method ever before conceived. The bowels are part of Nature's medium for eliminating poisons from the system. When these poisons have been removed, the blood stream becomes purified and performs its marvelous function of healing and correcting in all parts of the body.

"I investigated this instrument thoroughly before installing it, and in all my years of practice have never before been so impressed by any method of treatment. The results are positively astonishing. If you have tried everything else without relief, you have a surprise in store for you. You really can benefit greatly and not only feel the improvement at once but can actually see with your own eyes the positive evidence of what is causing your trouble.

"Let me impress you with some great truths. Curing is done by the blood stream. Medicines and treatments are effective only when they

(Footnote 2 is continued on page 202.)



the circular, was not a condition known to medical science. While admitting that the fecal matter in the colon contained some toxin, they testified that toxins are not absorbed in any considerable quantity into the blood stream from the colon. They denied emphatically that washing out the colon would purify the blood stream. They testified further that such toxins as entered the blood stream from the colon went first to the liver where they were rendered harmless. They testified that the function of the colon had very little, if anything, to do with the numerous diseases, mentioned in the circular. They also testified that a colonic irrigation would not cure hardening of the arteries, migraine, lumbago, colitis, gall bladder complications, high or low blood pressure, irregular heart, rheumatism, or any of the other named diseases. They testified that enemas or colonic irrigations are helpful in a limited sense only to relieve temporary discomfort caused by severe impaction, or as a preparation in case of some major abdominal surgical operations, but that colonic irrigations do not and cannot constitute an appropriate treatment for any of the diseases listed in the circulars.

[*Testimony for the Defense*]

The defense, on the other hand, offered the testimony of Dr. Neal Bishop, a doctor of chiropractic, and of J. O. Wolvin, a layman who was the manufacturer and distributor of the device in question. Dr. Bishop testified that the statements in the circulars were true; that he had treated patients with the device in connection with other therapy, such as chiropractic adjustments, diathermy

and others, and that its use was helpful. He did not testify specifically that its use had effected a cure in a single case of any of the diseases enumerated in the circulars. Certain X-rays which he had taken of patients before and after using the device were introduced to show, according to his contention, improved conditions in the posture and texture of the colon. Wolvin testified that the use of the device had cured him of a chronic case of asthma, and that when the asthma had a tendency to recur, his use of the device eliminated it. The only other evidence offered by the defense consisted of excerpts from several medical books, only one of which stated that colonic irrigation would aid in the treatment of any of the diseases named in the circular, other than some diseases of the colon. This in substance is the testimony upon which the judgment appealed from is based.

The excerpts from these medical books were introduced by the defense over the objection of the government. The court made the following findings of fact and conclusions of law:

[*Lower Court's Findings*]

Findings of Fact. (1) That the libelant has not offered any substantial evidence upon which to entitle it to judgment as prayed. (2) That the plate affixed to the colonic irrigator described in each of the Libels of Information and bearing the serial number and the words 'Tox-Eliminator—Tox-Eliminator Co.' does not constitute misbranding or mislabeling as set out in said Libels, or otherwise. (3) That the literature offered and received herein as

cause the system to purify the blood stream. Most ailments arise through toxins being thrown into the blood stream and a large share of this comes from the bowels.

"Polluted blood that helped cause an ailment, obviously cannot cure it.

"The bowels are one of Nature's chief agencies for purifying the blood stream. Hence, a thorough cleansing of the colon is helpful toward regaining health.

"And Here Is the Most Important of All

"A thorough cleansing of the colon is not possible through any other means than Tox-Elimination. Laxatives often inflame the bowel walls and leave a coating of infectious matter. Enemas and many types of colonic treatment often only partially cleanse the bowel. A daily bowel movement means absolutely nothing as to the condition of the intestinal tract.

"The following are some of the ailments almost invariably accompanied by intestinal toxemia and which respond to Tox-Elimination plus such other treatment as your condition requires:

"Arthritis, rheumatism, neuritis, high and low blood pressure, toxic heart conditions, ulcers of stomach, and bowels, colitis, chronic appendicitis, gall bladder and liver troubles, kidney and bladder troubles, asthma, migraine, toxic skin troubles, lumbago, and a host of ills that have heretofore been obscure.

\* \* \* \* \*

"Improper function of the colon is the most frequent contributing cause of intestinal toxemia and the following accompanying symptoms and ailments. They can now be successfully treated by our methods.

"Arthritis, Asthma, Colitis, Constipation, Excessive Fatigue, Foul Breath, Headache, Gall Bladder Complications.

"High and Low Blood Pressure, Indigestion, Irregular Heart, Kidney and Bladder Complications, Liver Complications, Lumbago, Menopause Disturbances, Muddy or Pimply Complexion, Migraine.

"Nervousness, Pruritis Ani, Rheumatism, Sinus Trouble, Run Down Condition, Shortness of Breath, Sleeplessness, Ulcers of Colon."



*U. S. v. One Device, etc., "Tox Eliminator"*

exhibits 1, 2, 3 and 4, and by this reference made a part hereof, constitutes labeling as such word is defined under Section 321m, Title 21 of the U. S. C. A.

**"Conclusion of Law.**

"As conclusion of law from the foregoing facts the court finds that the relief prayed for by the libelant in these proceedings should be and is denied. . . ."

*[Issues Presented]*

In general, the assignments of error present two issues which may be summarized as follows: First, the court erred in admitting in evidence excerpts from the medical treatises offered by the defendants. Second, the court's findings of fact are contrary to the clear weight of the evidence, and therefore erroneous.

*[Lower Court Admitted Incompetent Evidence]*

While the authorities are not in complete accord, the weight of authority is that medical books and treatises are not admissible to prove the statements therein contained.<sup>3</sup> The trial court erred in admitting and receiving in evidence excerpts from these books offered by the defendants for the purpose of establishing the truth of the statements contained therein.

*[Government's Evidence Was Substantial]*

While the trial court did not exclude the testimony of the five medical experts offered by the government, it was of the apparent opinion that their testimony was entitled to no consideration because they had neither tested the device in question nor had they observed it in operation. The court stated: ". . . my impression is that the government cannot come in here and rely upon the bald opinion of anybody who has never experimented with the thing in question. . . . So I am inclined to hold in this case that the government has failed to produce substantial proof of its charges . . . based upon, as I view it, reliance solely upon the opinion of the medical men." In other words, the court refused to consider the testimony of the medical experts because

he did not consider them qualified to testify concerning this device. Only in this way could the court have made Finding No. 1, "That the libelant has not offered any substantial evidence upon which to entitle it to judgment as prayed."

That these medical experts were competent and qualified to testify as to the matters in issue is clear. They were not disqualified merely because they had not used the device in question or had not seen it in operation. They testified not only that they were conversant with colonic irrigation, but also that they were familiar with the principles of the particular device in question. In its fundamentals, this device is not essentially different from any other circulatory apparatus for the purpose of giving an enema. The main function of all such devices is to introduce a flow of water into the colon for the purpose of cleansing it of accumulated waste matter. The fact that this device has a thermostatic control, a pressure valve, and may be attached to a faucet or may force the water farther into the colon, in no wise changes its essential or general functions. Being fully conversant with the principles of colonic irrigation and with the principles upon which this device operated, the testimony of these medical experts was competent<sup>4</sup> and constituted substantial evidence.

*[Appellate Court May Set Aside Erroneous Finding]*

Ordinarily an ultimate finding of fact by a trial court is binding upon the appellate court if sustained by the record, but if the finding is clearly erroneous or is based upon a misapplication of law to evidentiary findings, it is not binding upon the appellate court.<sup>5</sup>

The trial court's Finding No. 1, "That the libelant has not offered and substantial evidence upon which to entitle it to judgment as prayed", is clearly erroneous and must therefore be set aside.

*[Lower Court Did Not Separate Findings]*

The court's findings that the plate attached to the device and bearing the words "Tox Eliminator—Tox Eliminator Co., Inc.

<sup>3</sup> *U. P. Ry. Co. v. Yates*, 79 F. 584; *Miss. Power & Light Co. v. Whitescarver*, 68 F. 2d 928; *U. S. v. 50¾ Doz. Bottles, Sulfa-Seb*, 54 F. Supp. 759; Annotations 65 ALR 1102; 20 Am. Jur., Evidence, Sec. 968; 32 C. J. S., Evidence, Sec. 718.

<sup>4</sup> *Irwin v. Federal Trade Comm.*, 143 F. 2d

316; *U. S. v. 11¼ Doz. Packages, etc.*, 40 F. Supp. 208.

<sup>5</sup> *U. S. v. Armature Rewinding Co.*, 124 F. 2d 589; *Bratt v. Western Air Lines*, 155 F. 2d 850; *Sears, Roebuck & Co. v. Talge*, 140 F. 2d 395; *Bailey v. Smith*, 14 F. 2d 519.



Glendale, Calif. Ser. No. 513" does not constitute misbranding or mislabeling, finds support in the record when such label is considered separate and apart from the circulars in question. There is evidence that a colonic irrigation does eliminate some toxins from the colon. Under such testimony, a machine called a tox eliminator which tends to remove some toxins is not misbranded. The court found that the two circulars in question constituted labeling as defined in the Act. It did not, however, make a separate finding whether the statements contained therein were true or constituted mislabeling. It must, however, have been of the opinion that it did not constitute mislabeling, otherwise it could not have concluded as a matter of law that the relief prayed for should not be granted.

*[Lower Court Should Have Held That Circulars Constituted Mislabeling]*

In order for the government to prevail, it was not necessary to prove that all the representations in the two circulars were false. The charge of mislabeling would be established if the evidence proved any one of the representations to be false.<sup>6</sup> Here the substantial evidence by the government establishes the falsity, with minor exceptions, of practically every one of the broad claims set up in these circulars. The defendants offered positive evidence only as to one claim—asthma. One witness testified that the tox eliminator cured his asthma. No attempt was made to refute or contradict the government's evidence as to each of the other claims. The mere statement by Dr. Bishop that he had obtained good results from use of the device does not overcome the positive evidence of the medical experts. It must therefore be conceded that the government has established the falsity of many of these claims not only by the greater weight of evidence but also by all the evidence in the record. The finding of the trial court accordingly should have been that the two circulars in question constituted mislabeling.

*[Objection Is Not to Device]*

The objection is not to the use of this device or that it does not have a useful place in the art of healing. The vice is in the way and manner in which it is represented and the claims which are made for it in these circulars, which under the stipulation of facts and findings of the court

constitute a part of the labeling of the device. For the purpose of this opinion, it may be conceded that its use in flushing out the colon under expert supervision has a tendency to eliminate some toxins therefrom, thus preventing their entrance into the blood stream and thereby contributing somewhat to the purification of the blood and thus, in the ultimate, contributing to some extent to improvement in general health. But this is not what the labeling circulars state. In effect, they hold the machine out as a cure-all for all the ills that affect the human body. The authors of this literature apparently borrowed a leaf from the book of the ancients, who wanted to appease all the gods by erecting a statue to them and who, when they had erected a statute to all of the known gods, then, fearing that they might have overlooked one, erected another statue to the unknown god. Thus, the authors of "The Modern, Scientific Way to Health," after naming all the known ills of the body and representing that they would respond to the use of the tox eliminator, added this phrase, "and a host of ills that have heretofore been obscure." Nothing is overlooked. Relief is promised from every ill, whether known or unknown.

*[Ambiguous Statements May Mislead]*

It may be argued that the circulars do not promise a full cure in all of these cases, but only relief and improvement. But, as stated by the Supreme Court, "Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act."<sup>7</sup>

*[Lower Court Reversed]*

A casual reading of the circulars is sufficient to establish beyond doubt that the statements in these circulars would induce and were intended to induce the belief in the minds of many of the ailing and suffering that the tox eliminator promised absolute and general relief from all their ailments. The circulars are inherently dishonest and deceiving and constitute mis-

<sup>6</sup> *Goodwin v. U. S.*, 2 F. 2d 200.

<sup>7</sup> *U. S. v. 95 Barrels of Vinegar*, 265 U. S. 438.



branding within the meaning of the Act. The government established its case by substantial and preponderant evidence and is entitled to prevail. It follows that Finding No. 1 has no support in the record and

must be set aside. This finding of the trial court is therefore set aside, and the judgments are severally REVERSED, and the causes are remanded with directions to proceed in conformity with the views expressed herein.

---

**NATHAN AND MICHAEL GELLMAN, CO-PARTNERS  
DOING BUSINESS AS GELLMAN BROTHERS  
v. UNITED STATES**

United States Circuit Court of Appeals for the Eighth Circuit No. 13,412.

March 4, 1947. 159 F. 2d 881.

Affirming 65 F. Supp. 534. See page 173.

The case involved seizure proceedings against a shipment of rubber prophylactics alleged to be misbranded and adulterated because of the presence of holes. Tests of samples taken from the shipment, adverted to in the lower court's opinion, showed that the shipment included a substantial percentage of devices with holes and was properly condemned.

Sections 304 (a), 304 (d), 501 (c), 502 (a), Federal Food, Drug, and Cosmetic Act.

Although a larger percentage of the shipment did not have holes, the decree of condemnation preserved the right to the owners, under Section 304 (d), to separate the defective articles from the good pursuant to the provisions of the section.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Maurice Weinstein, for appellants.

Victor E. Anderson, U. S. Attorney (Theron L. Caudle, Assistant Attorney General, Clifford F. Hansen, Assistant U. S. Attorney, Vincent A. Kleinfeld, Attorney, Department of Justice, and James B. Goding, Attorney, Federal Security Agency, on the brief), for appellee.

Before SANBORN, WOODROUGH, and RIDDICK, Circuit Judges.

*[Nature of Proceeding]*

WOODROUGH, Circuit Judge: This appeal is to reverse a judgment of condemnation entered after trial by the court upon a libel of information by the United States against a shipment of rubber prophylactics transported in interstate commerce from Akron, Ohio, to Minneapolis, Minnesota, and there seized from appellants who are the owners. The articles are sold ostensibly for the purpose of preventing transmission of venereal disease and were labelled in part Xcellos' Prophylactics and in part Silver Tex Prophylactics, and the condemnation was ordered pursuant to the Federal Food, Drug, and Cosmetic Act, Sec. 304, 21 U. S. C. A. 334, upon the findings and conclusions of the court that the articles were adulterated within the meaning of 21 U. S. C. A. Sec. 351 (c) and were misbranded within the meaning of 21 U. S. C. A. Sec. 352 (a).

*[Samples Taken by Stipulation]*

Before the information of libel was filed, agents of the government purchased some of the articles and subjected them to tests, and after such filing and the seizure of the articles the parties stipulated in writing that the owners "cannot perfect the evidence required to proceed with said case until furnished with a sample of said seized property", and that representatives of the parties "on inspecting said seized property can best determine what sample is necessary to constitute a representative sample thereof" and "that the court may make the attached order" to permit examination and taking of representative samples of the articles. The court acted in accordance with the stipulation and issued the order agreed upon by the parties. In consequence all of the seized articles were not subjected to testing, and the findings and conclusions



of the court in respect to the charges of adulteration and misbranding were drawn from the testimony showing the nature, uses and purposes of the articles, the scale and processes of manufacture, the packing, labeling and shipment, and the results of the tests of the samples taken pursuant to the stipulation and order.

It appears that the articles are produced in quantities of millions by the manufacturer who has large investment in plant, machinery, material and product, and as the case is said to present the first instance of reported decision in the federal courts upon the application of the Act to interstate shipments of rubber devices of the kind involved through condemnation proceedings, the grounds relied on to avoid condemnation were fully developed and argued at the trial and on this appeal. The tests of the samples taken from the shipment showed that it included a substantial percentage of "leakers" having holes in them not discernible to the naked eye but of such size as to permit the passage of disease germs to and fro, which germs in the test carried to that extent remained alive and propagated. But it was also shown that a much larger percentage of the shipment in which the defective devices were indistinguishably commingled were not "leakers" and were, therefore, disease preventive and prophylactic to the extent limited by the uses for which they are adapted. The tests applied to the samples rendered them unfit for sale in ordinary course and in some instances caused them to burst.

*[Owner Had Right Under Decree To Repossess Goods]*

The judgment of condemnation preserves to the owners the right accorded by Sec. 334 (d) to repossess themselves of the shipment and separate the defective articles therefrom and upon bringing the shipment into compliance with the Act under designated supervision, to sell the same.

*[Contention of Claimant]*

The position taken by the owners is that the Act does not confer the power to order

condemnation of the whole shipment of commingled sound and defective articles; that the designation of the articles as Prophylactic was not "misbranding" even as to the "leakers" shown to have holes in them, and that the articles with the holes in the rubber of which they are composed, were not adulterated.

*[Trial Court Affirmed in All Respects]*

The trial court filed a written opinion with its findings and conclusions, and the same is reported in 65 F. Supp. 534. It presents the issues in the case and contains a fair statement of the evidence and the grounds of decision. It also reflects careful consideration of all matters of defense asserted for the owners and meets all substantial contentions for their position. We think it continues to meet such contentions, notwithstanding additional briefs and arguments submitted to and considered by us on this appeal. The additional contention that the samples were not representative of the shipment is not sustained. Our study of the record has satisfied us that the charges of the libel of information are supported by substantial evidence and that the provisions of the Act relied on authorized the court to enter the judgment of condemnation of the whole shipment subject to the conditions for repossession, separation and restoration of the shipment to compliance contained in the judgment. We think that the judgment in accordance with the opinion of the trial court (and with its separately filed findings and conclusions) was in all respects correct and proper, and although we recognize the importance of the case to the appellants and as a precedent, we think no good purpose would be served by making a re-statement of it from the record before us. We approve the statement of the case, the findings and conclusions, and the reasoning and decision as set forth in the opinion of the trial court, and find no error therein, and therefore affirm the judgment entered in accordance therewith.

Affirmed.



*U. S. v. One Article of Device Labeled "Spectro-Chrome"*

**UNITED STATES v. ONE ARTICLE OF DEVICE  
LABELED "SPECTRO-CHROME" AND  
ACCOMPANYING LABELING**

United States District Court for the District of Oregon. Civil No. 2855.

April 4, 1946, and May 22, 1946. 66 F. Supp. 754.

Reversed, 161 F. 2d 669. See page 210.

Certiorari denied, 332 U. S. 768 (1947).

See page 226.

Seizure proceedings were instituted against a device which was stipulated to have been misbranded when shipped in interstate commerce, but which was in the claimant's home and had been purchased by the claimant for the use of himself and his mother. The Government had a heavy burden to establish an exception to the general rule that a citizen's home is his castle, the security of which he may defend against all trespass.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The Constitutional guarantees against unreasonable searches and seizures are not limited to criminal proceedings, and the claimant could not be followed into his home and divested of his property.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The fact that the court had directed the marshal to return the device to the claimant pending trial did not destroy jurisdiction in the case.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Henry L. Hess, U. S. Attorney, and J. Robert Patterson, Assistant U. S. Attorney, for plaintiff.

Barnett H. Goldstein, Portland, Oregon, for defendant.

**Opinion of April 4, 1946**

*[This Is a Test Case]*

CLAUDE MCCOLLOCH, District Judge: Because I was told that the Department of Justice was making this a test case for many similar cases throughout the country, I took some time before ruling, although it seemed plain to me at the outset that defendant's constitutional rights had been invaded.

*[Facts]*

Defendant has purchased a Spectro-Chrome for the use of himself and his mother. The prospectus promises many cures. A color, or a combination of colors, will cure this, another combination of colors will cure that. The Government obtained a judgment that the machine was fraudulent in proceedings against the manufacturer and, because this machine was shipped in interstate commerce, the Government claims the right to take it from defendant, though he has bought and paid for it and is using it in his home. In fact, the marshal now has the machine in his possession, and this is a motion by the Government for permission to dismantle the machine for examination.

*[No Basis for Seizure]*

On what conceivable basis, under our Constitutional guaranties, can the Government deny to an adult individual the right to believe in and seek to cure himself of physical ailments by any means he chooses, so long as the means chosen is not inherently dangerous or harmful? I know many people who wear charms, including some who carry the lowly potato, to keep disease away, and I had always thought they had the right to do this. Incidentally, I have no doubt that many get help in this manner.

*[The Seizure Is Unlawful]*

I have not mentioned the special guaranties afforded by our law against intrusion into the home. This ground, I feel confident, could be shown to be sufficient to denounce the seizure in this case as unlawful.

Since writing what is above I have been advised that the Government is contemplating dismissing the case and returning the Spectro-Chrome to defendant's home. If that is done, it is likely that nothing more will need to be said.



[*Motion Denied*]

The Government's motion is denied.<sup>1</sup>

Opinion of May 22, 1946

[*Question at Issue*]

CLAUDE MCCOLLOCH, District Judge: This case having now been tried on the merits revives the question whether an inanimate object, inherently non-dangerous, which the owner thinks has therapeutic value, can be taken from him and his home, under process pursuant to the Federal Food and Drugs Act.

[*Device Admittedly Misbranded*]

It has been stipulated that the device was shipped in interstate commerce, labeled with false and misleading statements as to its therapeutic capabilities. Regardless, the owner testified that he was satisfied with the machine and wanted to keep it, and that he and his mother had both obtained help for certain disorders by using the machine. He testified further that he did not intend to make commercial use of the machine, did not intend to permit it to be used outside of his house or by others than his immediate family, constituting his parents and two brothers, both over twenty-one years of age and having had the same education as Claimant, in the grammar and high schools of the city of Portland, Oregon. The Claimant is twenty-three years old and was employed during the war in aircraft production, where he made use of the education which he had received in a technical high school.

[*Portion of Statute Involved*]

The Government relies on the words of the statute, that an article introduced into interstate commerce, with fraudulent representations as to its therapeutic value, may be seized and condemned "while in interstate commerce, *or at any time thereafter* . . ." 21 U. S. C. A. Sec. 334 (a). The italicized words, the Government contends, permit it to pursue and seize the article and

the literature containing the misleading statements, in a private home.

[*Facts*]

As shown by an earlier memorandum, the article was seized by the marshal on initial process, but I must now add that prior to the trial on the merits, just concluded, and subsequent to the preliminary memorandum, I directed that the Spectro-Chrome be returned to Claimant's home<sup>2</sup>—so that the case might present, as it now does, the clear cut issue, whether an instrument, harmless in itself, but accompanied by misleading literature as to the capabilities of the instrument, may be seized against his will from an adult male person, compos, who states that he is satisfied with the machine, is being helped by its use, and wishes to keep it.

[*The Right of a Citizen To Be Secure in His Home*]

I think this issue has not before been directly presented, and I think, as Judge Cooley said many years ago, that the question is—does this case constitute an exception to the general rule that the citizen's home is his castle, the security of which he may defend against all trespass? The Government has a heavy burden to establish the exception.

"Near in importance to exemption from any arbitrary control of the person is that maxim of the common law which secures to the citizen immunity in his home against the prying eyes of the government, and protection in person, property, and papers against even the process of the law, except in a few specified cases. . . ." (p. 425)

" . . . it would generally be safe . . . to regard all those searches and seizures 'unreasonable' which have hitherto been unknown to the law, and on that account to abstain from authorizing them, leaving parties and the public to the accustomed remedies." (p. 433)

Constitutional Limitations (7th Ed.)

<sup>1</sup> A valuable compilation of all of the Federal statutes providing for seizure is to be found in a note by Mr. Justice Brandeis, concurring in *Maul v. United States*, 274 U.S. 501, 518, 47 S.Ct. 735, 71 L.Ed. 1171 n. 21. And see a similar compilation by Mr. Justice Frankfurter in an appendix to his dissenting opinion in *Davis v. U.S.*, 66 S.Ct. 1273.

<sup>2</sup> The Government felt, I believe, that I had

destroyed jurisdiction in the case, when I directed the Marshal to return the Spectro-Chrome to Claimant pending trial. The analogy of Admiralty practice, where it is customary to permit a Claimant to resume possession of the seized article, by giving bond pending trial, indicates that the Government's position is not well taken. See Benedict on Admiralty, 16th Ed., Sec. 368.



*U. S. v. One Article of Device Labeled "Spectro-Chrome"*

This case does not present such an exception.<sup>3</sup> The case is nothing more than a well intentioned effort by high-minded and zealous officials to protect a man from what they deem to be folly, to the extent of following him into his home and family and there divesting him of property. This cannot be done, and I regret that I find myself in dissent from those Districts where, in connection with the nation-wide campaign to retrieve Spectro-Chrome machines, wherever found, contempt orders have been issued to private owners to compel delivery for condemnation.

To me, the wisdom of the ages means nothing if this humble citizen can be compelled against his will to yield access to his home to Federal officers to take from him and destroy a mechanical object, perfectly harmless in itself, which he thinks (whether rightly or wrongly makes no difference) is beneficial to him. My conception of the meaning of the Fourth Amendment is, that the citizen alone can unlock the doors to his dwelling, except in the rarest cases, and this is not one of the exceptions. Coke is credited with the maxim that "An Englishman's home is his castle" (which is morticed into the Fourth Amendment of our National Bill of Rights), and I cannot resist adding the imperishable words by Chatham, of a later English generation:

"The poorest man may, in his cottage, bid defiance to all the forces of the Crown. It may be frail; its roof may shake; the wind may blow through it; the storm may enter; the rain may enter; but the King of England may not enter; all his force dares not cross the threshold of the ruined tenement."

*The Right to Prescribe For Oneself*

Turning to the other major question in the case, no authority has been shown me

that supports the position of the Government, which, while admitting the Spectro-Chrome is not inherently dangerous, says in its brief: "It is claimed to be indirectly dangerous because the ailment of the user is aggravated by reason of the failure to consult competent medical authority."

This is admirable frankness on the part of the Government, but, as stated, it is supported by no authority, and I venture that it can be supported by none. I hesitate to labor the point, in opposition to this claim of paternal right to control the manner in which a person shall seek to cure himself. So many years, generations now, have been devoted to demonstrating that man is often his own best doctor, aside from the question of terrific import, of personal liberty, involved—it would be but stirring old waters, long calm, to review the successive struggle of healing groups and faiths, unconventional by majority standards.

More, tremendously more, is here involved—the right of the individual to select his own manner and means of treatment. The question is not, whether false and misleading statements were made to Claimant. The question is, what does he want to do about it? He says, "Nothing,—I am satisfied. I am being helped." But the Government answers, "We won't allow you to be satisfied. We won't allow you to help yourself. We know that you *may* be led into doing yourself harm, through relying too heavily on this machine, and thus not obtaining proper (by our standards) medical treatment." Without intending to give offense, I think no such proposition of paternal right in the field of public health has been advanced in modern times. At least I have been unable to find it in encyclopedias, treatises or law books.

<sup>3</sup> *Davis v. U.S.*, 66 S.Ct. 1256, is an exhaustive consideration of all phases of search and seizure.

*Oklahoma Press Pub. Co. v. Walling*, 66 S.Ct. 494, deals with seizure of documents in civil proceedings.

The Constitutional guaranties are not limited to criminal proceedings, as the Government seemed inclined to urge at the trial. At common law, an officer might not enter a dwelling, without the consent of the owner, for the purpose of serving a civil writ or process. 21 Am. Jur. Secs. 131, 136; 57 A.L.R. 211, Note; 129 A.L.R. 247, Note. *Takahashi & Osawa v. United States*, 9 Cir., 143 F. 2d 118, an opinion by my colleague, Judge Fee, is one of the leading cases of recent years in this field. What

might be called the Holmes-Brandeis law was made in the prohibition era. The enforcement policies of wartime agencies have raised Constitutional issues in this field anew.

<sup>4</sup> The makers of our Constitution "conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men".

These words by Mr. Justice Brandeis, taken from the dissenting opinion of the Justice in *Olmstead v. United States*, 277 U.S. 438 at 478, 48 S.Ct. 564, 572, 72 L.Ed. 944, 66 A.L.R. 376, are quoted by Mr. Frank E. Holman, a senior member of the Seattle bar, in an outstanding article published in the April 1946 number of the American Bar Association Journal, beginning at page 190.



*Conclusion*

An easy way of disposing of this case would have been to hold that the attempt to stretch the Government's power of seizure and condemnation under the commerce clause to an article in the hands of the ultimate consumer, raised grave constitutional questions which forbade such construction (*Federal Trade Commission v. American Tobacco Company*, 264 U. S. 298), but I have

preferred to meet head-on and to discuss the questions of security of one's dwelling and of personal liberty, which I regard as the true issues in the case. I have done this because I gained the impression during the war, and the impression has been strengthened since hostilities ended, that it is time for Federal judges to dust off the Constitution.

Judgment will be for the Claimant.

## UNITED STATES v. OLSEN

United States Circuit Court of Appeals for the Ninth Circuit. No. 11,403.

May 15, 1947. 161 F. 2d 669.

Reversing 66 F. Supp. 754. See page 207.

Certiorari denied, 332 U. S. 768 (1947).

See page 226.

A device which was misbranded when shipped in interstate commerce was seized in the home of its purchaser, where it was being used by the purchaser and his family. Having been misbranded when introduced into interstate commerce, the article was liable to be proceeded against and condemned at any time thereafter.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

It was immaterial, if true, that the claimant had paid for the device, had it in his home, and was satisfied with it, and that claimant did not intend to use it commercially and believed that he had been benefited by it. Such facts could not exempt the device from the provisions of Section 304.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The right of a person to prescribe for himself, if such a right exists, is subordinate to the rights of the Government under Section 304.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Section 304 is constitutional, was applicable to the situation before the court, and should be followed.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Theron L. Caudle, Assistant Attorney General, Washington, D. C., Henry L. Hess, U. S. Attorney, J. Robert Patterson, Asst. U. S. Attorney, Portland, Oregon (Vincent A. Kleinfeld and John T. Grigsby, Attorneys, Dept. of Justice, Washington, D. C., of counsel), for Government.

Barnett H. Goldstein, Portland, Oregon, for claimant.

Before GARRECHT, MATHEWS and BONE, Circuit Judges.

*[Nature of Proceedings]*

MATHEWS, Circuit Judge: On a libel of information, appellant, the United States, proceeded against an article called a Spectro-Chrome found in possession of appellee, William Ray Olsen, in the District of Oregon. Process was issued, and the article was seized. Appellee intervened as claim-

ant of the article, answered the libel and obtained an order directing that the article be returned to him, and it was so returned. Thereafter a trial was had, findings of fact and conclusions of law were stated, and a decree was entered dismissing the libel.<sup>1</sup> From that decree this appeal is prosecuted.

<sup>1</sup> *United States v. One Article of Device Labeled Spectro-Chrome*, D. C. Or., 66 F. Supp. 754.



## [Statute Involved]

The proceeding was under § 304 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 334, which provides:

"(a) Any article of food, drug, device,<sup>2</sup> or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce \* \* \* shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: \* \* \*

"(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; \* \* \*

"(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may \* \* \* direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; \* \* \*."

Section 502 of the Act, 21 U. S. C. A. § 352, provides:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling<sup>3</sup> is false or misleading in any particular."

## [Facts in Case]

These facts are undisputed: The article in question—the so-called Spectro-Chrome—was an instrument, apparatus or contrivance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man and hence was a device, within the meaning of the Act.<sup>4</sup> The article was transported in interstate commerce from Newfield, New Jersey, to Portland, Oregon, in June, 1945. When the article was introduced into and while it was in interstate commerce, its labeling<sup>5</sup> was false and misleading. Hence the article was misbranded, within the meaning of the Act,<sup>6</sup>

when introduced into and while in interstate commerce.

This proceeding was commenced on July 26, 1945. At that time, the article was not in interstate commerce. That, however, is immaterial; for, having been misbranded when introduced into and while in interstate commerce, the article was liable to be proceeded against and condemned at any time thereafter.<sup>7</sup>

It is immaterial, if true, that appellee had purchased and paid for the article, had it in his home, was satisfied with it and desired to keep it; that the article was not inherently dangerous or harmful; that appellee did not intend to use it commercially or to permit its use by persons other than himself and his mother and brothers, all of whom were over 21 years of age; and that appellee believed that he and his mother had been benefited by its use. Such facts could not and did not exempt the article from the provisions of § 304 of the Act, 21 U. S. C. A. § 334.

## [Right of Seizure Upheld]

It is said that appellee has a right to prescribe for himself and to "seek to cure himself of physical ailments by any means he chooses, so long as the means chosen is not inherently dangerous or harmful."<sup>8</sup> Such a right, if it exists, is subordinate to the rights of appellant under § 304 of the Act, 21 U. S. C. A. § 334.

There is no merit in the contention that § 304 of the Act, 21 U. S. C. A. § 334, is unconstitutional. The section is constitutional,<sup>9</sup> is applicable to this case and should be followed. Accordingly, the so-called Spectro-Chrome—the article proceeded against in this case—should be seized and condemned.

Decree reversed and case remanded for further proceedings in conformity with this opinion.

<sup>2</sup> Section 201(h) of the Act, 21 U. S. C. A. § 321(h), defines the term "device" as meaning "instruments, apparatus, and contrivances \* \* \* intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

<sup>3</sup> Section 201(m) of the Act, 21 U. S. C. A. § 321(m), defines the term "labeling" as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

<sup>4</sup> See footnote 2.

<sup>5</sup> See footnote 3.

<sup>6</sup> See § 502 of the Act, 21 U. S. C. A. § 352.

<sup>7</sup> See § 304 of the Act, 21 U. S. C. A. § 334.

<sup>8</sup> *United States v. One Article of Device Labeled Spectro-Chrome*, *supra*, 66 F. Supp. 755.

<sup>9</sup> *United States v. 935 Cases of Tomato Puree*, 6 Cir., 136 F. (2d) 523; *United States v. 62 Packages of Marmola Prescription Tablets*, D. C., W. D. Wis., 48 F. Supp. 878, affirmed in 142 F. (2d) 107; *United States v. Two Bags of Poppy Seeds*, 6 Cir., 147 F. (2d) 123. See, also, *Hipolite Egg Co. v. United States*, 220 U. S. 45; *McDermott v. Wisconsin*, 228 U. S. 115; *Seven Cases of Eckman's Alterative v. United States*, 239 U. S. 510.



UNITED STATES v. TWENTY CASES, EACH CONTAINING  
 12 DOZEN CARTONS, MORE OR LESS, OF JELL-O  
 VANILLA FLAVOR PUDDING

United States District Court for the Southern District of New York.  
 August 12, 1947. 77 F. Supp. 231.

In a seizure action, the Government moved to vacate, as improper, claimant's notice to take the deposition of the Commissioner of Food and Drugs. Section 304 (b) of the Act applies to the seizure of property by process *in rem*; thereafter proceedings in the action, which is civil in its nature, are governed by the Rules of Civil Procedure.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

In denying a motion to vacate, it was held that if, upon the examination, improper matters were inquired into, the Government had its remedy under Rule 37, Federal Rules of Civil Procedure.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

[*Motion To Vacate Notice Denied*]

BRIGHT, District Judge: Libelant's motion to vacate, as improper, claimant's notice to take the deposition of the Commissioner of Food and Drug Administration &c., dated December 9, 1946, is denied. Section 304 (b) (21 U. S. C. 334) of the Food, Drug, and Cosmetic Act, applies to the seizure of property by process *in rem*; thereafter proceedings in the action, which is civil in its

nature, is governed by the Rules of Civil Practice. *443 Cans of Frozen Egg Product v. United States*, 226 U. S. 172, 179; *Eureka Productions, Inc. v. Mulligan*, 108 F. (2d) 760, 761. The motion is to vacate the notice in toto, not to limit it. If upon the examination improper matters are inquired into, libelant has its remedy under Rule 37. Settle order on notice.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE,  
 MORE OR LESS, LABELED "SINUOTHERMIC," ETC. v.  
 UNITED STATES

United States Circuit Court of Appeals for the Fifth Circuit. No. 12033.  
 November 7, 1947. 164 F. 2d 245.  
 Reversed, 335 U. S. 355. See page 249.  
 See also pages 521 and 560.

In a seizure action to condemn devices because of allegedly false therapeutic claims made in printed matter shipped apart from the devices, it was held the printed matter had not accompanied the devices while they were in interstate commerce.

Sections 201 (m), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

It was doubtful that the printed matter, which looked like a small newspaper and contained testimonials from patients who had been treated at the institute conducted by the claimant, constituted labeling.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

In a criminal and forfeiture statute the meaning cannot be stretched.  
 Title, Federal Food, Drug, and Cosmetic Act.

Patients of the claimant should have been permitted to testify as to whether their external symptoms abated and their pains ceased after being treated by the device, since the evidence showed that diagnoses made by the claimant had not been made solely on the indications of the device but on all known methods of diagnosis.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.



The claimant, being a licensed naturopath, could express expert opinions, which might be believed by a trial judge.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Before SIBLEY, HUTCHESON, and HOLMES, Circuit Judges.

[Facts]

SIBLEY, Circuit Judge: Under the Food, Drug, and Cosmetic Act of 1938, Section 304, (21 U. S. C. A. § 334), sixteen electrical machines or devices were seized for condemnation in Ohio as having been misbranded when shipped in interstate commerce from Tampa, Florida, by appellant Fred Urbeteit to J. J. H. Kelsch at Cincinnati. The misbranding was alleged to consist in printed matter which accompanied them while in interstate commerce which was false and misleading in that it represented the machines as having therapeutic value in the diagnosis and treatment of stated diseases of man, whereas the devices were not effective for such purposes. Kelsch claimed six of them as his, and Urbeteit claimed ten of them as belonging to himself but rented to Kelsch. After trial, the case by consent having been transferred to Florida, a judgment of condemnation and destruction was rendered, with recovery of some \$1,150.64 costs. Urbeteit appeals.

The claims admit that six machines were sold by Urbeteit to Kelsch and shipped in interstate commerce as alleged, and that the ten others were rented and shipped to Kelsch by express, and that the printed matter was at the request of Kelsch sent by Urbeteit to Kelsch by parcel post; but deny that it was a labeling of the machines or accompanied them, and deny that its statements are false and misleading. The testimony, in great volume, related mostly to the falsity of the statements. We consider first, however, whether there was a misbranding proven under the Act.

[Written Matter Held Not To Accompany  
Devices]

Section 301 (a) (c) (21 U. S. C. A. § 331 (a) (c)) prohibits the introduction into and the receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and Section 304 (a) (21 U. S. C. A. § 334 (a)) provides for seizure and condemnation of such. It is not denied that these machines were devices within the Act. By Section 502 (a) (21 U. S. C. A. § 352 (a)) a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. A definition in Section 201 (21 U. S. C. A.

§ 321), which is the dictionary of the Act, is: "(m) The term labeling means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The last three quoted words are critical here. They make the term "labeling" broader than "label" as defined in paragraph (k), which includes only what is "displayed \* \* \* on the immediate container" of an article. How much broader? In *United States v. Research Laboratories*, 126 F. (2) 42, it was held that printed matter which did not travel with the article but was sent by the same shipper to the same consignee and received at the same time for use in connection with the article, "accompanied" it. But the same court in *Alberty v. United States*, 159 Fed. (2) 278, refused so to hold when the printed matter and the article were shipped two months apart and not simultaneously. Accepting those decisions as sound, the latter controls here. It is shown that machines valued at \$4300 were shipped July 25, 1945; value \$1200 August 14; value \$800 August 18; and value \$1200 Sept. 21. Kelsch testified that he had an understanding with Urbeteit that he would mail him some printed matter before he finally contracted for the machines, and that the matter was received about September, after the machines were delivered. It was found by the inspectors in Kelsch's consultation room, the machines being all in other rooms, on Sept. 5. The claim alleges the printed matter was mailed Sept. 1. It did not "accompany" in any fair sense either shipment. Both the amended libel and the second amended libel allege that the false leaflets "accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce." This is the exact language of Section 304 (a), the forfeiture provision of the statute, but it is shown not to be true of any shipment. The first three shipments went forward and were received by Kelsch, and put to work in his medical practice several weeks before any leaflets were sent. They did not accompany any of the devices while they were in interstate commerce. The last shipment went forward three weeks behind the leaflets, and was not accompanied by them. Accompany means



to go along with. In a criminal and forfeiture statute the meaning cannot be stretched.

*[Circular Appears To Be Advertisement]*

It may be doubted that the printed matter is in its nature a labeling for the machines. It looks like a small newspaper, entitled "The Road to Health, By Dr. Fred Urbeteit. Every subject pertaining to Health, Doctoring and Nursing is being taught at the College of Sinuothermic Institute, Inc., 307 West Euclid Ave., Tampa, Florida." To the left of this heading is a picture of Dr. Fred Urbeteit, President of Sinuothermic Institute, Inc., and to the right an attractive picture of the Institute and its grounds. Fifteen columns of fine print are below, consisting of testimonials and case histories of patients who had been treated at the Institute by Dr. Urbeteit, with unstinted praise of both. The Sinuothermic machine is mentioned and praised as an instrument of diagnosis and treatment, but there is no description or picture of the machine or any explanation of its operation, or any suggestion that it is for sale. The whole thing appears to be an advertisement for the Institute and Dr. Urbeteit, rather than something to accompany machines. Dr. Urbeteit is licensed as a practitioner of naturopathy in Florida. Dr. Kelsch is a chiropractor in Ohio. Dr. Kelsch became interested in Dr. Urbeteit's work and took a three weeks course at the Institute, and on the strength of it, on returning to Ohio, bought some of the machines, and rented others. He re-rented one to a patient to use at home, and sold one to another patient who moved to another State. The literature apparently was intended to advertise himself as following the methods of Dr. Urbeteit, rather than to explain or sell machines. Whether we ought to hold it a labeling of these machines if shipped simultaneously with them may be doubted. But if it could be called labeling, it is not proved by the present skimpy evidence that it accompanied the machines or any of them while they were in interstate commerce.

*[Error]*

Dr. Urbeteit vigorously contended that all he had said in "The Road to Health" was true. He offered in his claim, since no employee of the United States had any actual knowledge of his machine and only a few practitioners whom he had instructed, to conduct a series of tests of it in cooperation

with practitioners of medicine, osteopathy, chiropractic, and naturopathy approved by the court, on persons preferably before treated by medical practitioners without success, they to be examined before and after the test by physicians appointed by the court, during such period as the court should fix, their findings of the results to be evidence in the case. This was not done. Dr. Urbeteit at least seems convinced of the efficacy of his machine. He testifies that he was himself a suffering and distorted victim of arthritis deformans, and was helped to a degree which he described in detail, and exhibited his diseased joints to the court. He describes the construction of his machine, claims peculiarities in the winding of the electrical transformers in it which experimentally he found to produce currents peculiarly affected by diseased or congested bodily tissues, which when measured indicate where the trouble is, although often remote from the pain and other symptoms, and that it aided in locating the cause of trouble; and that a modified type of machine also was useful in treating many ailments. He testified in detail as to each case mentioned in "The Road to Health." He had thirty of his patients present whom he offered as witnesses to the benefits they had received, many of them being those mentioned in "The Road to Health." The judge refused to hear them, on the ground that being laymen they could not testify what was the matter with them and consequently could not say what they were relieved from, and that the diagnoses testified to by Dr. Urbeteit could not be accepted because he rested them on the use of his machine which the Government witnesses, who were men of high standing in medicine and in the electrical arts, had testified could not do what Dr. Urbeteit claimed. These rulings were error. One was based on the idea that Dr. Urbeteit had made his diagnoses solely on the indications of the machine. But his testimony as a whole was that he used all known methods of diagnosis, that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was, and it was then a matter of judgment as to what the disease was. He only claimed the machine to be an aid in diagnosing. The patients themselves could certainly know whether their external symptoms abated and their pains ceased. Urbeteit, being a licensed doctor of some twenty years practice, could



*U. S. v. 36 Drums, etc., of an Article Labeled in Part "Pop'n Oil," etc.*

express expert opinions. The judge might, after hearing all the evidence, prefer the expert opinions of the Government witnesses to those of Dr. Urbeteit, even as against the facts to which he and his witnesses might swear, but he should have heard all the competent testimony before making up his mind. The most eminent

physicians and scientists have in the past erred in their opinions, and opinions generally must yield to well proven contrary facts. The case ought to have been more fully tried.

The judgment is reversed and the cause remanded for further proceedings consistent with this opinion.

**UNITED STATES v. 36 DRUMS, MORE OR LESS, EACH  
CONTAINING APPROXIMATELY 400 POUNDS OF  
AN ARTICLE LABELED IN PART "POP'N  
OIL," WIL-KIN THEATRE SUPPLY,  
INC., CLAIMANT**

United States Circuit Court of Appeals for the Fifth Circuit. No. 11917.  
November 14, 1947. 164 F. 2d 250.

In a seizure proceeding to condemn mineral oil sold for use as a popcorn dressing, and artificially colored so that it resembled the color of melted butter, it was held that the adulteration of the product was not cured by its truthful labeling.

Sections 304 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

Even in the absence of a definition and standard of identity under Section 401, truthful labeling does not exempt an article from the provisions of Section 402 (b).

Sections 401, 402 (b), Federal Food, Drug, and Cosmetic Act.

The Federal Security Administrator is not required to promulgate definitions and standards of identity under all conditions.

Section 401, Federal Food, Drug, and Cosmetic Act.

Before SIBLEY, HUTCHESON, and HOLMES, Circuit Judges.

HOLMES, Circuit Judge: Pursuant to a libel filed by the United States, thirty-six drums of mineral oil, under the trade name of Pop'n-Oil, were seized and held in the custody of the Marshal, pending further orders of the court below respecting the same. The libel of information alleged that said oil was adulterated within the meaning of Section 342 (b) (2), (b) (3), and (b) (4), Title 21, of the United States Code, and that it was also misbranded within the meaning of Section 343 (b) of said code. After a trial upon the merits, the court vacated the seizure, ordered possession of the oil restored to the claimant, and dismissed the libel.

[Holding of Lower Court]

The court below held that the article seized was not harmful, that the drums were not misbranded, and that, in the absence of any definition or standard of identity prescribed by the Administrator, the

true labeling of the article was a compliance with the Act.

[Use of Mineral Oil]

The drums contained 99.3% mineral oil, artificial color and flavoring constituting the other seven-tenths of one per cent. This product was sold, shipped, and intended to be used as food. When popcorn is popped with Pop'n-Oil, the corn absorbs a substantial amount of the oil, so that 100 ounces of prepared popcorn would have in it from six to seven ounces of Pop'n-Oil. From a scientific standpoint, this was a very considerable amount, it being generally recognized that mineral oil has no food value. According to one dealer, who was a witness, the popcorn sold by him contained about 12½% of mineral oil. As to the harmful effects from the use of mineral oil as a food, the expert testimony (developed by questions from the court) is positive and uncontra-



dicted.<sup>1</sup> The product under seizure is of a rich yellowish color, and resembles the color of melted butter. The types of oil ordinarily used in the popping of corn are cocoanut, cotton-seed, and soybean, but during the war there was a shortage of these oils, and some distributors sold mineral oil for that purpose. Until the shortage of vegetable oils brought on by the war, mineral oil had never been used for popping corn. Mineral oil has no food value whatever, and therefore does not add to the food value of popcorn. A quantity of 6 or 7 per cent of any ingredient added to a food is a considerable rather than an infinitesimal amount. At the close of the Government's case, the claimant rested without adducing any evidence.

[*Government's Argument*]

Although the Government has abandoned its charge of misbranding, it has not abandoned any of its charges of adulteration but has concentrated its argument in this court on the following specific questions:

1. Whether the court erred in concluding that, in the absence of a definition and standard of identity promulgated under 21 U. S. C. 341, the truthful labeling of the article was a compliance with the Act.

2. Whether the court erred in concluding that the truthful labeling of the article exempted it from the provisions of 21 U. S. C. 342 (b) (3) and (4).

3. Whether the court erred in failing to find from the uncontroverted evidence that the article was adulterated within the meaning of 21 U. S. C. 342 (b) (3) and (4) when introduced into or while in interstate commerce.

The relevant statutory provisions are Sections 304 (a), 401, 402 (b) (3), and 402

(b) (4) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (a), 341, 342 (b) (3), and 342 (b) (4)).

[*Pop'n-Oil Adulterated*]

We think the adulteration of the product was not cured by its truthful labeling. Adulteration should not be confused with misbranding. The ultimate consumer of the popcorn probably never sees the labeling. The cartons containing the popcorn, sold in theatre vending machines, do not contain any statement showing that the popcorn dressing consists of 99.3% mineral oil, artificially colored and flavored. We think the Government's evidence sustained its allegations of adulteration under 21 U. S. C. 342 (b) (3) and (4).

[*Applicable Sections*]

Even in the absence of a reasonable definition and standard of identity, promulgated under 21 U. S. C. 341, truthful labeling does not exempt an article from the provisions of 21 U. S. C. 342 (b) (3) and (4), which provide that a food shall be deemed adulterated if damage or inferiority has been concealed in any manner; and also that a food shall be deemed adulterated if any substance has been added thereto or mixed or packed therewith so as to make it appear better or of greater value than it is.

[*Promulgation of Standards of Identity*]

In the instant case, mineral oil has been artificially colored and flavored to make it look like butter or vegetable oil. That mineral oil is inferior to melted butter on popcorn is plain. It is also inferior to cocoanut, soybean, or cotton-seed oil. To conclude that a food for which a standard of identity has not been promulgated is exempt from the economic adulteration provisions of the

<sup>1</sup> "Q. All right, with respect to the question that was put to you about the use of mineral oil as a making of salad dressing, and so forth, can you state whether or not the medical authorities approve the use of mineral oil in salads or anything else, any other—

"A. There is a report in the Journal of the American Medical Association for 1942, by the council on food and nutrition, council of the American Medical Association, in which they give an adverse report on the use of mineral oil in food, mineral oil—I mean salad oils, mayonnaise, and so forth.

"By the Court:

"Q. For what reasons? Do they say why it is?

"A. The reason they give is that mineral oil in the gastro-intestinal tract, in the alimentary tract, absorbs a very large quantity of carotin.

Carotin is the chemical substance which the body uses to synthesize vitamin A, which is an essential vitamin. It also interferes to a lesser extent with the absorption of vitamin A itself. It interferes also with the absorption of vitamin D, which is an essential vitamin. It interferes with the absorption of calcium and phosphates which are necessary for bone building, and also it has been found recently in experimental work that it interferes with the absorption of vitamin K, from the gastro-intestinal tract. Vitamin K is important and necessary for normal clotting of blood.

"Q. Do you know whether or not it is the general practice of doctors to prescribe the use of mineral oil in salads where they desire to reduce a person's weight?

"A. It has been done.

"Q. Isn't that rather a general practice?

(Footnote 1 is continued on page 217.)



*U. S. v. 36 Drums, etc., of an Article Labeled in Part "Pop'n Oil," etc.*

Act would result in rendering inoperative all of 21 U. S. C. 342 (b). The Administrator is not required to promulgate definitions and standards of identity for foods under any and all conditions. Administrative selectivity in such standardization is a part of his discretion and responsibility. To permit a class of foods not so selected to escape other applicable provisions of the law would create a loophole which the Act sought to avoid.

The evidence compels the conclusion that the oil sought to be condemned was artificially prepared to appear to be an acceptable popcorn dressing made from vegetable oil having a substantial food value, or from butter. It is a matter of common knowledge, of which the court may take judicial notice, that for use as food melted butter is superior to mineral oil.

The decree appealed from is reversed, and the cause remanded to the district court with directions to enter a decree of condemnation against the articles seized.

Reversed.

### Dissenting Opinion

SIBLEY, Circuit Judge, dissenting: Zeal for enforcement, I think, is here outrunning common sense and the true intent of the law. The seizure was made in 1943, in the midst of the late war. Theretofore the dressing for popped corn had been some animal or vegetable oil, such as melted butter, cocoanut oil, soybean oil, cotton-seed oil, or Wesson oil. Because of war conditions, cocoanut oil could not be had at all, butter and cotton-seed oil, soybean and Wesson oil, which had food value, became scarce and practically unobtainable because of the war demand for foodstuffs. Something else had to be substituted in the popcorn business, carried on at movie theatres and similar places of amusement, where popcorn is eaten in idleness and not for

nutriment. Mineral oil, which had long been used in salad dressings in place of olive oil and the like, and is still so used, came into general use for the popcorn dressing. It was colored light yellow, (which is the natural color of most oils and greases unless refined out), and was flavored to give the popcorn some taste. No point whatever is here made against adding the flavor. There is only the charge that a color was added which made it look more like melted butter. There is no evidence as to the color of cocoanut oil, cotton-seed oil, soybean or Wesson oil which also it was substituting. There is no evidence that the intent was to make it look like butter, or that any eater of popcorn thought it was butter, or cared. There was no effort at deceit while in interstate commerce, with which alone the federal Act is concerned. The seized drums were frankly labelled: "Pop N Oil, made from Liquid Petrolatum, Plastic Butter Flavor, Artificial Flavoring. Color Added. Distributed by Wilkin Theater Supply, Inc." The charge of misbranding is expressly abandoned, as it must be. Only adulteration is claimed. As to that it was on the trial expressly stated by government counsel: "If your honor please, we don't make any charge in this proceeding that the product is injurious to health or deleterious." It is true the court pressed questions as to that upon a witness as quoted in Note 1 of the opinion, but on the entire evidence he found that "the mineral oil was neutral and not harmful." The evidence is specific that in a nickel package of popcorn, which weighs one ounce, there would be only one-sixteenth of an ounce of dressing, say a half-teaspoonful. That is, by common experience with mineral oil, negligible. The law intends to keep deceitful or injurious mixtures out of interstate commerce, but it does not aim to exclude all mixtures. Where petrolatum is sold as

"A. I think it is quite general. I am not a practicing physician, however, and my opinion would be of a layman.

"Q. Was it in your opinion as a layman or a professional man that you have been discussing about the effect of mineral oil in the system?

"A. That is professional.

"Q. Beg pardon?

"A. That is an opinion as a specialist.

"Q. You consider yourself qualified to give those views and not qualified to give the latter?

"A. I would say that as most individuals become cognizant or aware of things that physicians do, and that is one of them. I know that.

"Q. Why did you testify in one instance as a layman and in another instance as a specialist,

that is the only thing I am asking?

"A. I was answering your question, Your Honor, to the effect that I do happen to know from reading and contact, that that is done. Now it is possible that if I had not been interested or were not interested in medical problems in general, I might not notice those things. But I do happen to know that that has been done and is being done.

"By the Court:

"Any other questions?

"By Mr. Lockerman:

"Q. Your special field is pharmacology?

"A. My special field is pharmacology.

"Q. Yes, sir. You may come down."



such, frankly stated to be artificially colored and flavored, and is perfectly harmless for the use intended, which is really more for entertainment than for feeding, it seems hypercritical to me at a time when war had forced all manner of substitutions in food, to condemn these drums of fifty gallons each as forfeited by law because of adulteration.

### Concurring Opinion

HUTCHESON, Circuit Judge, Specially Concurring:

I agree with my brother Sibley that in this case, "Zeal for enforcement, I think, is here outrunning common sense and the true intent of the law". I agree with my brother Sibley, too, that the case does not involve any charge that the product is injurious to health or deleterious. Therefore, it is plain that the opinion adduced by the judge himself and set out in the note to the majority opinion is immaterial and irrelevant to the issues in this case. Further being merely the statement of the opinion of the witness as to a report in the Journal of the American Medical Association, it is

hearsay and inadmissible and carries no weight whatever. I cannot therefore agree with the statement in the majority opinion that there is positive and uncontradicted testimony that the use of mineral oil as a food, as applied to this case, was, or could be harmful.

Notwithstanding, however, my opinion that the whole proceeding is a tempest in a teapot and that its bringing was an administrative error, I am compelled to agree with the views of my brother Holmes that, within the meaning of the statute under which the suit was brought, 342 (b) (3) and (4), the article in question was adulterated. It was adulterated under sub. sec. (b) (3) by having its inferiority to butter concealed by making it look like butter. It was adulterated under sub. sec. (b) (4) by being so colored "as to make it appear better or of greater value", that is by making it appear to be melted butter. I, therefore, concur in the conclusion the majority opinion reaches that the cause must be reversed and remanded with directions.

## UNITED STATES v. 9 BOTTLES \* \* \* "COLUSA NATURAL OIL," ETC. (COLUSA REMEDY CO., INTERVENOR)

United States District Court for the Northern District of Iowa,  
 Eastern Division. Civ. Nos. 406, 414-417, 372.  
 November 26, 1947. 78 F. Supp. 721.<sup>1</sup>

Libel for condemnation proceedings were instituted against "Colusa Natural Oil" on the ground that its labeling bore false therapeutic claims in the treatment of psoriasis and related disorders. There is no known certain permanent cure for psoriasis.

Sections 201 (g), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

There are a great many types of eczema and leg ulcers and many causes for them, and different kinds of treatment for eczema and leg ulcers are used by the medical profession at different stages of the diseases.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Athlete's foot is a fungus infection; in many cases the disease quickly responds to treatment; and in other cases the disease can be extremely resistant to treatment.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

The label of the product, when considered in its entirety, would be understood by a person of average intelligence as representing that the product would cure or alleviate psoriasis and related diseases of all types and kinds and at all stages thereof.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

---

<sup>1</sup> An appeal is pending in the United States Court of Appeals for the Eighth Circuit.



*U. S. v. 9 Bottles "Colusa Natural Oil"*

The product was worthless in the treatment of the diseases mentioned in the labeling at any stage of said diseases, and was misbranded and should be condemned.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Tobias E. Diamond, U. S. Attorney, William B. Danforth, Assistant U. S. Attorney, and Bernard D. Levinson, Attorney for the Food and Drug Administration, Washington, D. C., for libelant.

Walter Gleason, San Francisco, Cal., and B. F. Butler, Waterloo, Iowa, for intervenor.

HENRY N. GRAVEN, District Judge: Under the provisions of 21 U. S. C. A. Sec. 334 (b), it was stipulated between the libelant and the Intervenor Colusa Remedy Company that all of the above-entitled cases should be consolidated for trial in the Eastern Division of the Northern District of Iowa. Pursuant thereto, consolidated trials of the above-entitled cases were had before the court at the Federal Court House at Waterloo, Iowa, on November 13th, 14th, 17th and 18th, 1947. United States District Attorney Tobias E. Diamond, Assistant United States District Attorney Wm. B. Danforth and Bernard D. Levinson appeared as attorneys for the libelant. Walter Gleason and B. F. Butler appeared as attorneys for the Intervenor Colusa Remedy Company. On November 18th, 1947, the trials were completed and the cases submitted to the court and by the court taken under advisement. Now, to-wit, on this 26th day of November, 1947, the court now being fully advised in the premises makes the following Findings of Fact, Conclusions of Law and Order for Decrees.

#### Findings of Fact

1. The Intervenor Colusa Remedy Company is a corporation organized and existing under and by virtue of the laws of the State of Nevada with its principal place of business at Los Angeles, California.

2. The intervenor has for a number of years been shipping in interstate commerce bottles containing a liquid known as Colusa Natural Oil and bottles containing capsules which capsules are known as Colusa Natural Oil Capsules.

3. In each of the above-entitled cases the libelant has seized a number of bottles containing Colusa Natural Oil and Colusa Natural Oil Capsules by libel proceedings under the provisions of 21 U. S. C. A. Sec. 334 (a). In each case the bottles so seized had been shipped in interstate commerce by the intervenor.

4. The contents of each and all of the bottles so seized was intended for the treat-

ment of disease and as such constituted a drug under the provisions of 21 U. S. C. A. Sec. 321 (g) (2).

5. The libel proceedings in each case were instituted by the libelant upon the ground that the bottles proceeded against were misbranded under the provisions of that portion of 21 U. S. C. A. Sec. 352, which provides as follows: "A drug . . . shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular."

6. Each of the bottles of Colusa Natural Oil seized in the above-entitled cases had the following label attached:

"A natural unrefined petroleum oil intended for use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers. Directions: apply to affected parts and rub it in thoroughly morning and night. For open sores saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin oil can be diluted 50% with olive oil. Continue treatment until skin is smooth and comfortable. We suggest in treatment of Psoriasis, Eczema and Leg Ulcers using Colusa Natural Oil externally as above directed and Colusa Natural Oil Capsules internally as directed on bottle containing Colusa Natural Oil capsules."

7. Each of the bottles containing Colusa Natural Oil Capsules seized in the above-entitled cases had the following label attached:

"A natural unrefined petroleum oil in capsules intended for internal use in treatment of Psoriasis, Eczema, Leg Ulcers. Directions: For adults start with one capsule at bedtime then after 3 days change to one capsule after each meal until skin is smooth and comfortable. For children under ten—one capsule or its content squeezed into milk or water at bedtime until skin is smooth and comfortable. We suggest use of capsules as above directed in conjunction with liquid Colusa Natural Oil applied externally to affected parts as directed on bottles containing Colusa Natural Oil in liquid form."



8. In each of the above-entitled cases the Colusa Remedy Company has appeared and asked for the release of the seized bottles and the dismissal of the cases upon the ground that the bottles so seized were not misbranded under the provisions of 21 U. S. C. A. Sec. 352 referred to.

9. The composition of the liquid contained in the seized bottles labeled Colusa Natural Oil is identical with that of the liquid in the capsules contained in the seized bottles labelled Colusa Natural Oil Capsules. The composition of the Colusa Natural Oil and Colusa Natural Oil Capsules seized in each case is identical with that seized in each of the other cases. The issue as to misbranding is the same in all of the above-entitled cases.

10. Natural unrefined petroleum oil is one and the same as crude petroleum. The liquid contained in the seized bottles labeled Colusa Natural Oil is crude petroleum. The liquid in the capsules contained in the seized bottles labeled Colusa Natural Oil Capsules is crude petroleum. As to whether the intervenor purchased the crude petroleum contained in the bottles involved in this case in the open market or obtained the same from a particular oil well or oil field does not definitely appear.

11. Psoriasis, Eczema, Leg Ulcers and Athlete's Foot are diseases of the skin. Wherever hereafter the term "patient" is used, it means one who has one of those diseases.

12. The causative factor or factors of Psoriasis are obscure and difficult of ascertainment. Psoriasis is a very difficult and frequently baffling disease to treat. Manifestations of the disease will appear and disappear without any apparent reason of cause. There is no known certain permanent cure for Psoriasis.

13. There are a great many types of Eczema and many causes for it. There are different stages of the disease. In some cases of Eczema the causative factor or factors are easily ascertained. In other cases of Eczema the causative factor or factors are difficult of ascertainment. In other cases of Eczema the causative factor or factors cannot be ascertained. In cases of Eczema where the causative factor or factors are unknown, they may cease, and the disease cease without the patient or his doctor being aware of what brought about the cessation of the disease. In the cases of

Eczema where the causative factor or factors are unknown, they may become inactive or less active and the patient may have a partial cure or have relief without the patient or his doctor being aware of what brought about such partial cure or relief. Different kinds of treatment for Eczema are used by the medical profession for different types of the disease. Different kinds of treatment for Eczema are used by the medical profession at different stages of the disease.

14. There are many types and kinds of Leg Ulcers. There are many causes for Leg Ulcers. A great many Leg Ulcers are chronic in nature and difficult to cure. In a great many cases the causative factor or factors of Leg Ulcers are difficult of ascertainment. In a great many cases of Leg Ulcers the causative factor or factors cannot be ascertained. Different kinds of treatment for Leg Ulcers are used by the medical profession for different types of the disease. Different kinds of treatment are used by the medical profession at different stages of the disease. Where the causative factor or factors of Leg Ulcers are unknown, they may cease and the disease cease without the patient or his doctor being aware of what brought about a cessation of the disease. Where the causative factor or factors of Leg Ulcers are unknown, they may become inactive or less active and the patient may have a partial cure or have relief without the patient or his doctor being aware of what brought about such partial cure or relief.

15. Athlete's Foot is a fungus infection. In a great many cases the disease quickly responds to treatment. In other cases the disease can be extremely resistant to treatment. In some cases the disease is apparently resistant to any treatment. In some cases the human body will, over a period of time, build up sufficient resistance to the disease so as to overcome it. In the present cases the matter of the disease of Athlete's Foot is involved only as to Colusa Natural Oil, as the labels on the bottles containing Colusa Natural Oil Capsules do not refer to Athlete's Foot.

16. The Intervenor Colusa Remedy Company contends: (a) that it does not claim that Colusa Natural Oil will cure Psoriasis, Eczema, Athlete's Foot and Leg Ulcers, or that Colusa Natural Oil Capsules will cure Psoriasis, Eczema and Leg Ulcers; (b) that it does claim that those remedies will



assist or relieve in the treatment of the diseases referred to; and (c) that the most that can be claimed as to the labels in question is that they only represent that the remedy will assist or relieve in the treatment of the diseases referred to and no more.

17. The label on each of the bottles of Colusa Natural Oil in question, when considered in its entirety, would be understood by a person of average intelligence who was suffering from one of the diseases referred to therein, and who was seeking a remedy for such disease as representing that if he would use Colusa Natural Oil as directed, that such Oil would cure or alleviate Psoriasis, Eczema, Athlete's Foot and Leg Ulcers of all types and kinds and at all stages thereof.

18. The label on each of the bottles in question containing Colusa Natural Oil Capsules, when considered in its entirety, would be understood by a person of average intelligence who was suffering from one of the diseases referred to therein, and who was seeking a remedy for such disease as representing that if he would use Colusa Natural Oil Capsules as directed, that such capsules would cure or alleviate Psoriasis, Eczema and Leg Ulcers of all types and kinds and at all stages thereof.

19. There is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil, when used externally, will cure Psoriasis, Eczema, Athlete's Foot or Leg Ulcers or will alleviate such diseases, or will give relief from such diseases or will assist in the treatment of them. The Colusa Natural Oil in question is worthless and without value in the treatment of any or all of said diseases at any stage thereof. The external use by a patient will, under certain conditions, have the harmful effect of causing infection in an open sore.

20. There is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil Capsules, when used internally, will cure Psoriasis, Eczema or Leg Ulcers or will give relief from such diseases, or will alleviate such diseases or will assist in the treatment of them. The Colusa Natural Oil Capsules in question are worthless and without value in the treatment of any or all of said diseases at any stage thereof.

21. The contents of Colusa Natural Oil Capsules, when taken internally, do not absorb into the human system except to an insignificant extent. When the contents of Colusa Natural Oil Capsules are introduced into a human stomach, they have a slightly irritating and cathartic effect and tend to retard the absorption of food.

22. The labeling of the bottles of Colusa Natural Oil seized in the above-entitled cases is false and misleading.

23. The labeling of the bottles containing the Colusa Natural Oil Capsules seized in the above-entitled cases is false and misleading.

#### Conclusions of Law

1. That this court has jurisdiction of the subject matter in each of the above-entitled cases and of the parties thereto.

2. That the bottles of Colusa Natural Oil seized in each of the above-entitled cases are misbranded within the provisions of 21 U. S. C. A. Sec. 352 (a).

3. That the bottles containing the Colusa Natural Oil Capsules seized in each of the above-entitled cases are misbranded within the provisions of 21 U. S. C. A. Sec. 352 (a).

#### Order For Decrees

It is hereby ordered that a decree shall be entered in each of the above-entitled cases decreeing:

1. That the bottles of Colusa Natural Oil seized in each case are misbranded within the provisions of 21 U. S. C. A. Sec. 352 (a) and condemning them as such.

2. That the bottles seized in each case containing Colusa Natural Oil Capsules are misbranded within the provisions of 21 U. S. C. A. Sec. 352 (a) and condemning them as such.

3. Awarding against the Intervenor Colusa Remedy Company in each of the above-entitled cases the costs provided for under 21 U. S. C. A. Sec. 334 (e).

#### Order

It is hereby ordered that these Findings of Fact, Conclusions of Law and Order for Decree shall be filed in each of the above-entitled cases as the Findings of Fact, Conclusions of Law and Order therein.

It is further ordered that similar decrees shall be filed in each of the above-entitled cases.



338 CARTONS, MORE OR LESS, OF BUTTER, 1209 CARTONS,  
MORE OR LESS, OF BUTTER, AND 318 CARTONS,  
MORE OR LESS, OF BUTTER, BOWSER SALES  
& TRADING CORPORATION, CLAIMANT v.  
UNITED STATES

United States Circuit Court of Appeals for the Fourth Circuit. No. 5629.  
December 24, 1947. 165 F. 2d 728.

In a seizure suit, the butter proceeded against was found to be adulterated under Section 402 (a) (3), and the district court ordered it condemned. The claimant thereupon moved that the court deliver the product to it to be manufactured into butter oil. An appeal was taken from a denial of the motion. The order appealed from was a final order and appealable.

Sections 304 (a), 304 (d), 402 (a), Federal Food, Drug, and Cosmetic Act.

It is clearly within the sound discretion of a trial court whether the reprocessing of a condemned article is to be allowed, and such decision can be reversed on appeal only for a manifest abuse of discretion.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

The evidence showed that the process proposed by the claimant for renovating the butter (which contained maggots, fly eggs, etc.) would remove only the insoluble insect parts, and that the portion of the contamination which had become soluble could not be separated. There is no scientific method by which the insect fat could be detected in the finished product, but such fat would probably be in the finished product.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The courts have recognized that adulteration of foodstuffs may be so slight as to come under the maxim *de minimis non curat lex*, but no case has been found wherein food found to be filthy under the Act has not been condemned.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The jury had been properly instructed that, in order to make a finding that the butter proceeded against consisted in part of a filthy substance, it must be satisfied that the filth was present in a substantial degree.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The review of the circuit court of appeals was limited to the inquiry as to whether the action of the district court in overruling the claimant's motion was a clear abuse of judicial discretion, that is, arbitrary action unwarranted by the facts of the case; no such abuse of discretion was disclosed.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

W. G. Stathers (George Richardson, Jr., on brief), for appellant.

Vincent A. Kleinfeld, Attorney, Department of Justice, (T. Vincent Quinn, Assistant Attorney General, and Leslie E. Given, U. S. Attorney, on brief), for appellee.

Before SOPER and DOBIE, Circuit Judges, and CHESNUT, District Judge.

DOBIE, Circuit Judge: This appeal is the result of three libel proceedings instituted by the United States (hereinafter called the Government) under the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 334 (a), (hereinafter called the Act) in which the Government sought the seizure and condemnation of three lots of

butter owned by the Bowser Sales & Trading Corporation of Sisterville, West Virginia, (hereinafter called the claimant) and shipped in interstate commerce. The proceedings were consolidated and tried before a jury in the District Court of the United States for the Southern District of West Virginia. The jury returned a verdict in



favor of the Government on virtually all issues, and the District Court, finding the butter to be adulterated within the meaning, and in violation of the Act, 21 U. S. C. A. 342 (a) (3), ordered it condemned and forfeited to the United States. The claimant thereupon moved the court "to deliver the condemned article to it, pursuant to Section 334 (d), Title 21, United States Code, for the purpose of salvaging or manufacturing same into butter oil so the same will be made to conform to and with the provisions of the Federal Food, Drug, and Cosmetic Act." After hearings were had and evidence taken upon this motion, the lower court overruled it, and this appeal is taken from that denial of the motion.

[Holding of Lower Court]

At the outset, the Government in its brief contends that the order from which the claimant appeals is not a final decision within the meaning of 28 U. S. C. A. § 225 and hence is not reviewable by this Court. This point was not strongly urged upon us in oral argument. We think that the judgment of the District Court is final and appealable. Its decree directed the condemnation and forfeiture of the butter, denied the claimant's request to reprocess the butter in order to make it fit for human consumption, but granted the claimant's motion that the product be released to it for manufacture into soap stock. Certainly this order terminates the litigation between the parties on the merits of the case and fully determines the rights and liabilities of the claimant and the Government with respect to the property in controversy. Nothing remains to be done except to perform certain ministerial tasks prescribed by the court order.

[Issue]

It is to be emphasized that this appeal is not from the decree of condemnation but only from that part of the judgment which denied the claimant permission to salvage the butter by converting it into butter oil fit for human consumption. The pertinent part of the Seizure Section of the Act, 21 U. S. C. A. 334 (d), provides:

"Any food \* \* \* condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct \* \* \*; *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a

good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Chapter under the supervision of an officer or employee duly designated by the Administrator, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond."

It, therefore, is clearly within the sound discretion of the trial court whether the reprocessing of a condemned article is to be allowed. *United States v. 1322 Cans of Black Raspberry Puree*, 68 F. Supp. 881, *United States v. 143 Packages of Nue-Ovo*, 51 F. Supp. 1; *United States v. Two Cans of Oil*, 268 Fed. 866. And, of course, this decision of the trial judge can be reversed by us on appeal only for a manifest abuse of discretion by the trial judge.

[Facts]

From the evidence submitted at the condemnation trial the jury found that the butter in question consisted in part of decomposed substance and in part of filthy substance in substantial enough quantity to be adulterated within the terms of the Act, 21 U. S. C. A. 342 (a) (3). As was stated by the District Court in its opinion:

"The evidence which was before the jury on the question of decomposed substances related mainly to mold mycelia count, which, as to each churn of butter, was found to be in excess of that permitted in practice by the Food and Drug Administration.

"The evidence on the question of filth was of two kinds; first, that much of the cream which found its way into the vats of the company for the manufacture of butter contained, before filtering, some flies, maggots, mites, fly eggs, and in rare cases, rodents; and secondly, that the manufactured butter had in it numerous hard insect parts, feathers, barbules, mites, rodent hairs, maggots and fly eggs, for the most part invisible to the naked eye, and discernible only with the use of a microscope."

At the hearings on the motion for reprocessing the butter the Government, through the evidence of qualified experts of the Food and Drug Administration, showed that insects, mites and fly eggs contain fatty and oily substances as inherent constituents of their anatomy; and that



when butter or cream becomes contaminated with any such insect material the fatty portions, being soft and liquid at ordinary temperatures, dissolve into the fat of the cream or butter and completely merge therewith. The trial judge, therefore, refused to allow the salvage of the butter because no process was shown, or in fact even known, which would remove soluble insect fats from the butter oil. The testimony was to the effect that the process proposed by the claimant for renovating the butter would remove only the insoluble insect parts and that the portion of the contamination which had become soluble could not be separated. There actually is no scientific method by which the insect fat or oil could even be detected in the finished product since it had become amalgamated with the butter fat.

[Claimant's Argument]

As a result, the claimant advances the contention that inasmuch as the presence of insect fats cannot be detected, no showing has been made that such soluble filth is present in the condemned butter, and, consequently, all that is necessary in order to salvage the butter is to remove the insoluble extraneous matter, which claimant alleges is the only filth that has been actually proved to be in the product. We think that this argument is well answered by the District Judge:

"Whole insects, maggots and fly eggs were in the cream. It was subjected to heating, agitation, and filtration under pressure. It is hardly reasonable to suppose that soft bodies, made softer by the application of heat, would not be crushed by the mechanical processes of filtration. Since the butter fat passed through the filters, it is an inescapable conclusion that insect fat also passed through."

The claimant next contends that even though insect fat should be present in the butter after reprocessing, it would be in such an infinitesimal quantity that it could not contaminate the butter oil. It is true that the courts have recognized that adul-

teration of foodstuffs may be so slight as to come under the maxim *de minimis non curat lex*. See *A. O. Andersen & Co. v. United States*, 284 Fed. 542; *United States v. 184 Barrels Dried Whole Eggs*, 53 F. Supp. 652; *United States v. 133 Cases of Tomato Paste*, 22 F. Supp. 515; and administrative tolerances for decomposition have been adopted by the Food and Drug Administration. No tolerance for filth in butter, however, has even been established under the Act. Claimant is unable to cite any case wherein food found to be filthy within the meaning of the Act has not been condemned.

[Instruction to Jury]

The jury was properly instructed that in order to make a finding that the butter consisted in part of filthy substance it must be satisfied that the filth was present in a substantial degree. It was also instructed that if it found the hard parts of an insect's body in the butter, the normal inference would be that the soft parts of the insect were also in the butter. The jury made a finding of filth in the butter, and since the soluble insect parts could not be removed by the reprocessing method, we are unable to say that this insect fat should be treated as coming within the *de minimis* rule.

[Power of Trial Judge]

It was for the District Judge to say whether the claimant should be allowed to reprocess the butter and then offer it to the public as fit for human consumption. We cannot substitute our judgment for his in the determination of this question. Our review is limited to the inquiry as to whether his action in overruling the claimant's motion was a clear abuse of judicial discretion, that is, arbitrary action unwarranted by the facts of the case. *Home Owners' Loan Corp. v. Huffman*, 134 F. (2d) 314; *In re A. Roth Co.*, 125 F. (2d) 396. The record on this appeal does not disclose any such abuse of discretion on the part of the trial judge.

The judgment of the District Court is accordingly affirmed.



**SALAMONIE PACKING CO. v. UNITED STATES**

United States Circuit Court of Appeals for the Eighth Circuit.

No. 13549. January 6, 1948. 165 F. 2d 205.

Certiorari denied, 333 U. S. 863 (1948).

Seizure proceedings were instituted against canned tomato juice on the ground that it was adulterated in that it consisted, in whole or in part, of a decomposed substance by reason of the presence of decomposed tomato material. Section 402 (a) (3) means that food which contains filthy, putrid, or decomposed matter is to be deemed adulterated whether or not it is fit for food.

Sections 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

If the section needs amendment, in the public interest, to guard against the possibility of the destruction of wholesome food by the Government, the problem is one for Congress.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Israel Treiman and William C. Bachelder (Lashly, Lashly, Miller & Clifford and Bachelder, Bachelder & Fife were with them on the brief), for appellant.

Drake Watson, U. S. Attorney (Vincent A. Kleinfeld was with him on the brief), for appellee.

Before SANBORN, WOODROUGH, and COLLETT, Circuit Judges.

[*Facts*]

SANBORN, Circuit Judge, delivered the opinion of the Court: The Government, pursuant to Section 304 (a) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. A. Section 334 (a), instituted five separate libels against certain cases of canned tomato juice shipped in interstate commerce by appellant. In each libel the Government sought the condemnation of the accused tomato juice on the ground that it was adulterated within the meaning of 21 U. S. C. A. Section 342 (a) (3), in that it consisted, in whole or in part, of a decomposed substance by reason of the presence of decomposed tomato material. The libels were consolidated. The appellant in its answer denied that its product was "adulterated," and alleged that it was "neither harmful nor poisonous, but good and safe for human consumption." On motion of the Government, the court struck from the answer the allegation that the juice was fit for human consumption.

[*Verdict in Lower Court*]

The case was tried to a jury. The Government's evidence showed that the accused tomato juice contained mold and decomposed tomato material. There was no evidence that the juice was unfit for food. Some evidence was introduced by appellant to show that the juice was not offensive to the sense of smell or taste, and that no decomposed material was observable to the

naked eye. At the close of the evidence, appellant moved for a directed verdict on the ground that there was no evidence that the accused product was unfit for food. The District Court denied the motion. The jury returned a verdict for the Government. From the judgment and decree, directing the destruction of the tomato juice, this appeal is taken.

[*Appellant's Contentions*]

The contentions of appellant are (1) that an article of food must be proved to be unfit for food before it can be adjudged to be "adulterated" within the meaning of Section 342 (a) (3) of Title 21, U. S. C. A., and (2) that evidence of fitness for food is admissible in determining whether an article of food is "adulterated."

The pertinent language of Section 342 is as follows:

"A food shall be deemed to be adulterated—

"(a) \* \* \* (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food \* \* \*."

The following paragraph of appellant's brief concisely states its position relative to this language:

"The section of the statute referred to above provides that food is to be deemed adulterated if 'it consists in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food.'



The last phrase of the above provision 'or is otherwise unfit for food' was placed in the statute when the law was re-enacted in 1938. It is appellant's contention that this phrase qualifies the preceding part of the sentence; and means that the product must not only be decomposed but must be decomposed to the extent of being unfit for food; and that, therefore, the burden is on the government to prove that the product is unfit for food before the government can demand the destruction of the product."

[*Food Need Not Be Unfit  
for Consumption*]

Virtually the same argument which appellant makes here was presented to and rejected by the Circuit Court of Appeals of the Tenth Circuit in the case of *United States v. 1851 Cartons, etc.*, 146 Fed. 2d 760. We think that the court in that case has fully demonstrated that the statute means that food which contains filthy, putrid, or decomposed matter is to be deemed adulterated, whether or not it is fit for food. Ap-

parently, for years, food processors have been endeavoring, unsuccessfully, to secure a ruling which would compel the Government, in cases such as this, to prove that an accused article of food contained so much decomposed matter as to make it unfit for human consumption. See *United States v. Two Hundred Cases of Adulterated Tomato Catsup*, (D. C., D. Oregon) 211 F. 780, 782-783 and other cases cited in *United States v. 1851 Cartons, etc.*, *supra*, page 761 of 146 F. 2d.

If the statute in question needs amendment, in the public interest, to guard against the possibility of the destruction of wholesome food by the Government, the appellant's remedy is to call the matter to the attention of Congress.

We conclude that the District Court did not err in ruling that the question whether the tomato juice was fit for food was not and could not be made an issue in the case.

The judgment appealed from is affirmed.

## UNITED STATES v. ONE ARTICLE OF DEVICE LABELED SPECTRO-CHROME

United States District Court for the District of Oregon. No. 2855.  
 March 15, 1948. 77 F. Supp. 50.  
 See pages 207 and 210.

On petition of the Government for the issuance of an order of seizure against a misbranded device held in its owner's home, based on the mandate of the circuit court of appeals, it was held that the order must be issued "though it is one of the most unpleasant tasks I have had to perform as judge."

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

[*Petition To Issue Order of Seizure*]

McCULLOCH, District Judge: I have before me the petition of the United States Attorney to issue an order of seizure in this case based on the mandate of the Circuit Court of Appeals, 161 F. 2d 669. Of course I must issue the order, though it is one of the most unpleasant tasks I have had to perform as judge. The policy of entering private homes to seize articles is governmental madness. Just because you have authority does not mean that you have to use it. Indeed, the greatness of the United States Attorneys throughout the country,

many of whom I have met, is that they resist so many demands from the multitude of bureaus and agencies that are presently employed to govern the people. I may add the United States Attorney has been allowed no choice in this case.

[*First Adoption of Country-Wide Policy*]

This is the first time, I believe, that a country-wide policy of entering homes has been adopted. I am sad that the policy has to be enforced in this court.

[*Order of Seizure Issued*]

The order of seizure will issue.



## RESEARCH LABORATORIES, INC. v. UNITED STATES

United States Circuit Court of Appeals for the Ninth Circuit.  
No. 11,624. April 2, 1948. 167 F. 2d 410.  
Certiorari denied, 335 U. S. 843 (1948).

Seizure proceedings were instituted against a proprietary drug on the ground that it was misbranded because of false and misleading therapeutic claims made in accompanying labeling. The court declared that the case of *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, had been heard on a demurrer and involved the Postmaster General's power to decide what was in reality a medical question, as to which he would presumably have no professional training. It cannot be assumed that the Supreme Court, in the *McAnnulty* case, intended to reach out a dead hand over the power of Congress to pass legislation in the future setting up a well-equipped Federal agency capable of arriving at a professional conclusion as to the adulteration or misbranding of drugs.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The Federal Security Agency has at its disposal almost unlimited professional resources with which to carry out its investigations. The impact of the *McAnnulty* case has been carefully limited in later decisions.

Sections 502 (a), 702 (a), Federal Food, Drug, and Cosmetic Act.

A jury may consider testimony as to actual experiments conducted by qualified physicians and surgeons.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

The testimony of experts as to the consensus of scientific opinion is also relevant.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

Expert testimony, even in its broadest sense, where the witness has neither tested the product nor purports to report the consensus of medical opinion, is admissible on the question of the therapeutic value of a drug.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

There is a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods. In the instant case, the Government had presented factual evidence from documents and lay witnesses of definite untruths and half-truths contained in the labeling of the product.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

The doctrine that advertisements as a whole may be completely misleading, although every sentence separately considered is literally true, is specifically incorporated in the Act by Section 201 (n).

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The question of good faith or fraudulent intent is not involved in a case under the Act. This does not mean, however, that the Government, in presenting to the jury a fair and complete picture of the claimant's activities, must sedulously avoid adducing any evidence of fraud, disclosed, for example, in advertising material not constituting part of the labeling.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.

The design of the present Act was to make the provisions against misbranding stricter and not more lenient than they had been in the pre-existing law. The new Act was not designed to provide the misbrander of drugs with additional technical loopholes for escape, but to batter down those already existing.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.



The Act is remedial, and should be liberally construed so as to carry out its beneficent purposes.

Title, Federal Food, Drug, and Cosmetic Act.

The comprehensive terms of the statute condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements which are not technically false or which may be literally true.

Title, Federal Food, Drug, and Cosmetic Act.

In any case where an article is alleged to be misbranded because the labeling is misleading in any respect, it is made mandatory by Section 201 (n) that the jury "shall" take into account omissions or suppressions, notwithstanding the fact that no reference to the section appears in the pleadings or pretrial order.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

A trial court, in a libel for condemnation action under the statute, exercises its sound discretion as to whether the condemned article shall be released under bond. It was held that the trial court, in the instant case, had exercised its discretion soundly and judiciously; and that the interests of the public would be better subserved by keeping the product proceeded against off the market altogether.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Justin N. Reinhardt, Portland, Ore., for appellant.

J. Charles Dennis, U. S. Attorney, Seattle, Wash.; Harry Sager, Assistant U. S. Attorney; and Arthur A. Dickerman, Attorney U. S. Food and Drug Administration, Tacoma, Wash.; for appellee.

Before GARRECHT, MATHEWS and HEALY, Circuit Judges.

GARRECHT, Circuit Judge: In four cases consolidated for trial, judgments and decrees were entered condemning and ordering destroyed quantities of a proprietary drug known as "Nue-Ovo" and certain written material alleged to constitute the labeling thereof. The action of the court below was taken pursuant to libels alleging misbranding, under 21 U. S. C. A. § 352 (a). From the judgments and orders referred to, the present appeals have been taken by the intervenor below, as claimant of the property seized.

The appellant, an Oregon corporation, has engaged in the manufacture, sale, and distribution of proprietary drug products known as "Nue-Ovo," "Sal Trag," and "Burvidin" continuously since 1925. The formulas of the products have been changed from time to time, and the merchandise now under seizure differs from products of the same name involved in previous litigation.

Nue-Ovo is sold direct to consumers. In concentrated form, called "Sal Trag," it is sold to licensed physicians. The products are manufactured at Portland, Oregon, and shipped to purchasers and distributors in

most of the states west of the Mississippi River. The appellant's direct sales program involves extensive use of advertisements in daily and weekly newspapers and similar publications. In general, these advertisements solicit mail inquiries regarding the effectiveness of Nue-Ovo in the treatment of arthritis, neuritis, rheumatism, sciatica, and lumbago, to which inquiries the appellant replies by mail. The advertisements referred to are not, of course, part of the labeling.

In November, 1944, a libel was filed in the United States District Court for the Western District of Missouri, Western Division, pursuant to which there were seized by the United States Marshal about 600 units of Nue-Ovo, each unit containing three bottles. Some of the unit cartons are labeled in part:

"Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Dandelion, Kola Nut, Ginseng, Althea, Cascara and Licorice.

"This is the regular Nue-Ovo Formula to which have been added laxatives.

"Less than one-half of one per cent Sodium Benzoate added as a preservative."



Other unit cartons are labeled in part:

"This is the regular Nue-Ovo formula to which have been added Cascara, Licorice, and Sodium Salicylate. Less than one-half of one per cent Sodium Benzoate added as a preservative. Vitamin B1 added."

The libel alleges that the 600 units were shipped by the appellant on or about June 27, 1944, and August 2, 1944, from Portland to Crown Drug Company, Kansas City, Missouri.

Pursuant to the same libel there were also seized at the same time stocks of circulars entitled "information on Nue-Ovo and its value in Arthritic and other Rheumatoid symptoms." The circulars were alleged to have been shipped in interstate commerce on or about April 7 and August 8, 1944, from Chicago, Illinois, by Nue-Ovo, Inc.—not the appellant herein—to the Crown Drug Company at Kansas City.

The libel alleges that:

"The article is misbranded within the meaning of 21 U. S. C. A. § 352 (a) in that the statements in the attached Exhibits 'A' and 'B' which appear in the labeling of the article . . . are false and misleading in this, that such statements represent and suggest and create in the mind of the reader thereof the impression that the article of drug, Nue-Ovo, is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, whereas, the article is not effective in the treatment of such conditions."

Other seizures were made later pursuant to libels following the same general pattern as the foregoing.

The proceedings were all removed to the court below, where they were consolidated for trial in accordance with the provisions of 21 U. S. C. A. § 334 (b).

The court below entered a pre-trial order which specified as an agreed fact that "the labeling alleged in the several libels constituted the labeling of the product seized."

The agreed issues were stated in the pre-trial order as follows:

1. Whether or not the Nue-Ovo under seizure is ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.

2. Whether or not the labeling under seizure suggests to the user that the Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.

3. Whether or not the product is misbranded by reason of the labeling.

The appellant admitted that the labeling represented the product to be effective. Thus the misbranding and the ineffectiveness of the product were the issues to be litigated.

Summarized, the appellant's attacks upon the judgment below are as follows:

1. The court below erred in submitting issues to the jury, since every statement in the labeling as to the effectiveness of the product is a statement of opinion, and at the conclusion of the case the record showed nothing more than a difference of opinion among qualified medical experts as to the effectiveness of the product.

2. The court erred in receiving testimony intended to show a misleading of the witnesses by material that was not part of the labeling seized.

3. The court erred in instructing the jury as to the elements to be taken into account in determining whether the labeling is misleading, under 21 U. S. C. A. § 321 (n), *infra*.

4. If it should be held that the court did not err in giving an instruction based upon 21 U. S. C. A. § 321 (n), *infra*, the court's denial of the appellant's motion for the release of the product under bond was an abuse of discretion.

5. As applied by the court the statute is unconstitutional.

If the first four objections urged by the appellant are found to be untenable, the fifth must fall of its own weight and need not be discussed.

1. *The Rule in the McAnnulty Case*

The appellant bases its first contention upon a line of decisions commencing with *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, 105-106. There the court said:

"As the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud. Unless the question may be reduced to one of fact as distinguished from mere opinion, we think these statutes cannot be invoked for the purpose of stopping the delivery of mail matter."



Although the *McAnnulty* case was decided four years before the passage of the original Food and Drugs Act of June 30, 1906, c. 3915, 34 Stat. 768, the doctrine there announced was applied to the misbranding of drugs in *United States v. Johnson*, 221 U. S. 488, 498-499 (1911), and in *Seven Cases of Eckman's Alterative v. United States*, 239 U. S. 510, 517 (1916).

## 2. Three Limitations to the *McAnnulty* Rule

It should be borne in mind, however, that the *McAnnulty* case, *supra*, was heard on a demurrer and involved the Postmaster General's power to decide what was in reality a medical question, as to which he would presumably have no professional training.

It cannot be assumed that the Supreme Court intended to reach out a dead hand over the power of Congress to pass legislation in the future setting up a well-equipped Federal agency capable of arriving at a professional conclusion as to the adulteration or misbranding of drugs "when introduced into or while in interstate commerce." 21 U. S. C. A. § 334 (a). In the *McAnnulty* case the court not only pointed out that "as the case arises on demurrer, all material facts in the bill are of course admitted," but throughout the opinion doubt was expressed as to the qualifications of a *postmaster general* to pass on medical questions.

In the excerpt which we have already quoted, the Supreme Court expressed the view that "the efficacy of any special method [of treatment of disease] is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud." Again, on page 105 of the opinion, referring to the place of electricity in therapeutics, the court pointedly asks: "Was this kind of question intended to be submitted for decision to a Postmaster General, . . .?"

On the following page, the court thus summarized its holding as to the Postmaster General's power under the mail fraud statutes:

"Other instances might be adduced to illustrate the proposition that these statutes were not intended to cover any case of what the Postmaster General might think to be false opinions, but only cases of actual fraud in fact, in regard to which opinion formed no basis."

Even in that case, however, the court conceded that the Postmaster General

might make a showing that fraud was being committed:

"In overruling the demurrer we do not mean to preclude the defendant from showing on the trial, if he can, that the business of complainants as in fact conducted amounts to a violation of the statutes as herein construed."

Cf. *Leach v. Carlile*, 258 U. S. 138, 139, 140.

And in *Seven Cases of Eckman's Alterative v. United States*, *supra*, 239 U. S. at page 518, Mr. Justice Hughes said:

"It cannot be said, for example, that one who should put inert matter or a worthless composition in the channels of trade, labeled or described in an accompanying circular as a cure for disease when he knows it is not, is beyond the reach of the law-making power. Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose."

In contrast to the meager technical facilities for the determination of medical questions possessed by the Postmaster General—at least at the time that the *McAnnulty* case was decided—we find that the Federal Security Agency has at its disposal almost unlimited professional resources with which to carry out its investigations in the enforcement of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. A. § 301 *et seq.* Typical of this elaborate set-up are the provisions of 21 U. S. C. A. § 372 (a):

"The Administrator is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Agency or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Administrator as an officer of the Agency." [Italics Supplied]

As we shall disclose in our discussion of the evidence hereinafter, this extensive professional implementation authorized by the statute under consideration was fully utilized in the case at bar.

In view of the foregoing, it could well have been reasoned *a priori* that the impact of the *McAnnulty* case would be carefully limited in later decisions. And that is precisely what has occurred.

As was said in *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos* [DC Minn.],



53 F. Supp., 746, 759, heavily relied upon by the appellant itself:

"Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the *McAnnulty* case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the *McAnnulty* rule, courts should give recognition to this advancement."

(a) *Jury May Consider Testimony as to Actual Experiments*

Much of the appellee's evidence in the instant case consisted of "controlled clinical studies" conducted by eminently qualified physicians and surgeons.

Dr. Frances Baker, Director of the Department of Physical Medicine at the University of California, whose professional qualifications appear to be highly impressive, testified at great length regarding a clinical study that she made in 1944 with the Nue-Ovo that contained cascara and licorice, but not B-1 and salicylate. The study was made on patients in the orthopedic clinic at the University of California Hospital. At the end of two months, five of the patients "were no better at all" and "one felt better." As the result of her studies, Dr. Baker testified that she thought that Nue-Ovo "offers us nothing that is of value in the treatment of arthritis." She expressed similar opinions as to Nue-Ovo's effectiveness in cases of lumbago, sciatica, neuritis, and rheumatism, and stated that the addition of sodium salicylate and Vitamin B-1 in quantities found in one type of Nue-Ovo would not "give us any value whatever."

Dr. John H. Wheeler is a practicing physician in Kansas City, Missouri, and is on the teaching staff of the University of Kansas, in Kansas City, Kansas. In 1944, at the request of the Food and Drug Administration in Kansas City, he made a study of Nue-Ovo in the Out-Patient Department of the University of Kansas. The type of Nue-Ovo that he used was that containing cascara and licorice, without the B-1 and salicylates. Six patients were asked to continue the medicine for six weeks. Dr. Wheeler testified that the medicine had "no effect whatsoever" on three patients, and two patients stated that they "were of the opinion . . . that they were no worse." On the day of his return, the

sixth patient "felt that he had definitely improved while taking his Nue-Ovo," but "was complaining of some new pains involving both knees." This sixth patient, however, made that report ten months after starting the medication with Nue-Ovo, and still had some of the six weeks' supply of the medicine left.

In 1940, Dr. Wheeler "had experience" with Nue-Ovo with no added cascara or licorice with twenty-three patients, nine of whom took the preparation for as long as three months. Some took it for as short a period as two weeks, in one case because the discomfort was so great that the patient desired some other type of medication. Of the twenty-three cases, there were eighteen upon whom Nue-Ovo had no "effect whatsoever," three were "questionable, in that perhaps their symptoms had improved slightly over the . . . previous period of nine months," and "two were definitely of the opinion that they felt better." Based upon his total experience with the product in 1944 and the product in 1940, Dr. Wheeler's opinion was that, with or without cascara, licorice or sodium salicylate or thiamine in the amount stipulated, Nue-Ovo's "effectiveness is nil" in the treatment of arthritis, rheumatism, lumbago, neuritis, and sciatica.

Testimony of experts that is based upon tests or experiments made by them does not come within the ambit of the *McAnnulty* rule. In *Elliott Works v. Frisk* [DC Iowa], 58 F. (2d) 820, 825, the problem was fully and lucidly discussed:

"Complainants are mistaken in their claim that the only evidence introduced as against them was mere opinions of witnesses and that the opinion of the expert for the government should not be considered as substantive evidence. In this contention complainants rely upon the case of *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, 23 S. Ct. 33, 47 L. Ed. 90. The facts here are entirely different from what they are in that case, which arose on a demurrer wherein all the material facts averred in the bill were admitted for the purpose of the hearing. It may be conceded that the court there held that mere matters of opinion on which witnesses might vary in their conclusions would not substantiate a fraud order such as is here under consideration; but the finding of the solicitor in this case is not based on opinions, but upon a scientific investigation, findings, and tests made by the United States Bureau of Standards. Opinions of experts



when founded upon known scientific facts are not to be considered the same as opinions of laymen, but are considered by the courts as substantive evidence. [Cases cited.] However, the evidence upon which the facts here were found was not alone based upon such scientific opinions, but upon tests made and facts actually disclosed by independent research of experts in an outstanding scientific bureau of the national government."

See also *Kar-Ru Chemical Co. v. United States* [CCA-9], 264 Fed. 921, 928; *United States v. Lesser* [CCA-2], 66 F. (2d) 612, 616; *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos, supra*, 53 F. Supp. at pages 758-759.

(b) *Testimony of Experts as to Consensus of Scientific Opinion Is Also Relevant*

Dr. James M. Dille, professor of pharmacology and assistant dean of the School of Medicine of the University of Washington, while on the witness stand went down the list of ingredients of Nue-Ovo and categorically reported that scientific "investigation" by "doctors or pharmacologists" has shown that many of the ingredients have no "action" as drugs. For example concerning plume thistle, the first ingredient listed in the statement of "agreed facts," Dr. Dille said: "It has no action that doctors or pharmacologists can find, at all."

Again, as to ginseng, another Nue-Ovo ingredient, Dr. Dille said: "... as modern pharmacology developed and they made all sorts of investigations on ginseng, they found that it is absolutely without any potent principal of any value to medicine."

It is generally agreed that testimony as to the consensus of medical opinion may be considered in drug-misbranding cases. In *United States v. Dr. David Roberts Veterinary Co.* [CCA-7], 104 F. (2d) 785, 788, the court said:

"In support of this count the testimony disclosed that the product does not contain ingredients which would be effective as a treatment for shoeboils or poll evil; that it has no value in the treatment of enlarged glands; and that no drug or mixture of drugs is known to the profession generally, or agreed upon the consensus of veterinary opinion, that can do all of the things claimed by this label.

"The record also discloses that the professional witnesses for the government

testified that the opinions expressed by them were in accord with the consensus of veterinary opinion.

"In the instant case, the question was reduced to one of fact, as distinguished from mere opinion, [cases cited], and, as defendants' testimony made for conflicting evidence, a question of weighing the evidence was presented. To weigh the evidence is not within the power of this court."

See also 28 C. J. S. Druggists § 12 k (2), page 531.

(c) *Even Opinion Testimony as to Therapeutic Value Is Admissible*

In this circuit and elsewhere, it has been held that expert testimony even in its broadest sense—i.e., where the witness has neither tested the product nor purports to report the consensus of medical opinion—is admissible on the question of therapeutic value.

In *John J. Fulton Co. v. Federal Trade Commission* [CCA-9], 130 F. (2d) 85, 86, certiorari denied, 317 U. S. 679, we said:

"The findings have support in the testimony of expert witnesses called by the Commission. But the petitioner argues that since none of the experts had prescribed Uvursin or observed its effects in concrete cases their testimony was incompetent and inadmissible. We think otherwise. The witnesses were shown to possess wide knowledge in the field under inquiry. There is no reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petitioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify." [Cases cited]<sup>1</sup>

The same doctrine has been followed in misbranding cases tried before juries. In *Goodwin v. United States* [CCA-6], 2 F. (2d) 200, 201, cited by us with approval in the *Fulton* case, *supra*, it was said:

"Upon the trial of the issue of fact joined by the libel charging the misbranding of mineral water and the answer of the intervener, expert evidence may be properly admitted. If it appears from the testimony of a witness upon preliminary examination that he is learned in the science of chemistry or has been regularly and legally admitted to the practice of medicine, and that he has know-

<sup>1</sup> See also *Irwin v. Federal Trade Commission* [CCA-8], 143 F. (2d) 316, 324; *Charles of the*

*Ritz Distributors Corporation v. Federal Trade Commission* [CCA-2], 143 F. (2d) 676, 678-679.



ledge of the drug elements contained in the article transported in interstate commerce and their efficacy or lack of efficacy as curative agents, used either separately or in combination in the treatment of the diseases specified on the label, his opinion on the subject is competent evidence regardless of whether he has had actual experience or observation of the effect of the use of such drugs in the exact form in which they are transported in interstate commerce. *The weight of his evidence is a question for the jury.* [Italics supplied]<sup>2</sup>

The evidence in this case included the three types that we have discussed hereinabove: Testimony by experts based on (a) tests made of the product itself; (b) the consensus of medical opinion as to the various ingredients used in Nue-Ovo; and (c) the expert witnesses' personal opinions regarding the effectiveness of such ingredients. Altogether, there was ample evidence to support the verdict of the jury.

3. *Much of the Factual Evidence of the Appellee Consisted of Other Than Medical Testimony*

It will be remembered that in the *Eckman's Alterative* case, *supra*, Mr. Justice Hughes has pointed out that Congress has "recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods." In the instant case, the appellee presented factual evidence of definite untruths and half-truths contained in the labeling of Nue-Ovo. This evidence did not come from medical experts but from documents and from lay witnesses.

The labeling purports to quote from a letter written by Mrs. Fred Anderson, of Albany, Oregon, in part as follows:

"I wish to say that after taking Nue-Ovo I feel like a new person, inasmuch as my nerves are 100% better—no trace of Neuritis left and a general built-up condition."

This letter is one of a group that appears on the labeling, with the following notation: "Original letters on file in office. Copies may be obtained on request."

In a "motion to produce documents," the appellee demanded that the originals of a number of these letters be produced by the appellant, including the letter attributed to Mrs. Anderson.

Mrs. Eleanor M. Feldman, president of the appellant, was unable to produce the originals of at least four of the letters, including that of Mrs. Anderson. Instead, "copies" were offered. Mrs. Feldman explained that in moving from one location to another, some of the appellant's documents were lost, an entire steel file having disappeared from her office.

Mrs. Anderson gave a deposition in which she stated that after taking the first three or four bottles of Nue-Ovo she thought that her "time had come;" that she didn't think it had done her any good; that she did not have neuritis, but arthritis; that she did not write the letter, and could not account for it: "How on earth they got my name is more than I know." A former employee of the appellant asked Mrs. Anderson to give him a testimonial, but she refused, according to her deposition.

Another part of the Nue-Ovo labeling contains two "before-and-after" photographs of H. J. Shermer of Leaburg, Oregon, flanking the facsimile of a notarized letter by him extolling the merits of that nostrum. The photograph taken "before" Nue-Ovo shows Mr. Shermer in an emaciated condition, his weight being given as 110 pounds. The post-Nue-Ovo photograph shows Mr. Shermer as he appeared eighteen months later, weighing 165 pounds.

In his letter, Mr. Shermer stated that he was first afflicted with arthritis fifteen years prior to the date of writing, October 8, 1934. After taking Nue-Ovo for eighteen months, Mr. Shermer wrote, he was able to attend to his business, pursue his hobbies of hunting and fishing, "and enjoy life generally."

C. W. Frazier, of Newburg, Oregon, who had been for sixteen years the sheriff of Harney County, Oregon, himself a sufferer from arthritis or rheumatism, or possibly both, saw the photographs and the facsimile letter of Mr. Shermer. With the traditional skepticism of a peace officer, the former sheriff decided to investigate. He called upon Mr. Shermer and found him sitting by a trailer, with his feet on a padded stool and a pair of crutches at his side.

Mr. Frazier wrote to the appellant about his "disappointing visit" to Mr. Shermer. In reply, Mrs. Feldman "explained" that the "back-set" was due to the complete extrac-

<sup>2</sup> See also 28 C. J. S. *id.*



tion of Mr. Shermer's teeth at one time and to overwork. Mrs. Feldman further wrote that Nue-Ovo was helping Mr. Shermer "for the third time," and she felt certain "that now that he is free of responsibility and that he and Mrs. Shermer can have a little more leisure time, he will make his third recovery."

Still not satisfied with the outcome of the Shermer investigation, Mr. Frazier called upon Mrs. Feldman in person. Mr. Frazier testified:

"Well, the conversation got a little exciting a time or two. Mrs. Feldman sort of accused me of trying to make her out one damn liar, so she said. Why I told her, I said, 'Mrs. Feldman, I wouldn't think of putting it that way', but I said 'Your advertising I still question quite a little.'"

Finally, the Nue-Ovo labeling contains an "analysis of ingredients," with the prefatory explanation that it is based chiefly on the *United States Dispensatory*, the *Pharmacopoeia*, and various textbooks on pharmacology.

It is here that half-truths enter the picture. While the label's "analysis" followed part of the language of the above-named authorities somewhat closely, and sometimes verbatim, there were significant omissions in the excerpts. Here are a few of the deleted portions:

[Ginseng] "The extraordinary medicinal virtues formerly described as [ascribed to] Ginseng had no other existence than in the imagination of the Chinese."

[Horehound] "It has, however, been almost completely abandoned by physicians."

[Salvia or Sage] "For what reason this condiment was admitted in the N. F. is not obvious. While the ancients say it is highly esteemed, there is no evidence that it possesses therapeutic virtues, and it is practically never prescribed by physicians."

[Lappa or Burdock] "There is not sufficient reason, however, to believe it has any medicinal virtues."

The apocryphal or misleading testimonials and the scientific half-truths in the labeling alone make out a case of actionable misbranding. As was said by the Supreme Court in *Donaldson v. Read Magazine*, Slip Opinion, page 10, decided on March 8, 1948: "Advertisements as a whole may be completely misleading although every sentence separately considered is literally true.

This may be because things are omitted that should be said, . . ." As we shall see hereafter, this doctrine is specifically incorporated in the statute now under consideration. See 21 U. S. C. A. § 321 (n), *infra*.

#### 4. *There Was No Error in the Admission of Evidence of Misleading Material Not Part of the Labeling*

The appellant complains that the appellee sought to show that its "lay witnesses" had been misled by material that was not part of the labeling seized. Particular criticism is directed against the questioning of "witness after witness" regarding a newspaper advertisement in which Anna Pautz invited persons suffering from arthritis, neuritis, rheumatism, sciatica and lumbago to communicate with her; and also regarding a letter in her handwriting and with her signature, stating that she had been benefited by using Nue-Ovo. The appellant concedes that testimony showed that the letter, in each instance that it was sent out, had not been written personally by Mrs. Pautz, but was the reproduction of a letter originally written and signed by her.

To say that the appellant did not deal frankly with the public in connection with the Pautz letter would be a distinct understatement. Further details are necessary to bring out the complete shadiness of this publicity project, which in the oral argument counsel for the appellant declined to defend.

Mrs. Pautz, who was 76 years old at the time she testified, became a stockholder in the appellant about 1924, before using Nue-Ovo for arthritis. She testified that it cured her. She has never taken Nue-Ovo since 1923 or 1924.

Beginning in 1945, there appeared in Portland newspapers, and later in other publications in the United States the following advertisement:

#### "Rheumatism and Arthritis

"I suffered for years and am so thankful that I am free from pain and able to do my work that I will gladly answer any one writing me for information. Mrs. Anna Pautz, P. O. Box 825, Vancouver, Wash.

"Pd. Adv. Nue-Ovo Laboratories, 403 N. W. 9th Ave., Portland 9, Ore."

At first, Mrs. Pautz financed the running of the advertisement and the rental of the post office box out of her own funds. Later, however, according to Mrs. Feldman's tes-



timony, the appellant apparently took over the advertising costs, through a block advertising agency:

"Mrs. Pautz is quite an old lady, and a very sweet old soul. When I found she was running it, I certainly wouldn't permit her to pay for it."

A month or two after the advertisement first appeared, in a Portland newspaper, Mrs. Pautz composed and wrote out the letter in question, no one helping her with it. Her motive for doing so was just because she "wanted to help somebody."

The letter contained the salutation "Dear Friend," and advised sufferers from arthritis and rheumatism to visit or write to the appellant's headquarters. In the letter Mrs. Pautz gave the Vancouver post office box as her mail address.

Mrs. Pautz testified that at the time she wrote the letter, she did not own any stock in the appellant, having sold her shares to one of her sisters.

Mrs. Pautz actually lives in Portland, which has been her home for fifty-eight years. The evidence adduced by the appellant as to why Mrs. Pautz gave the Vancouver address is contradictory. Mrs. Pautz herself testified that she never used the Vancouver box for her personal mail and that Vancouver was selected—

"Because there is a girl working in the laboratories at Vancouver, Washington, and she could pick up the mail and bring it to the laboratories."

Mrs. Feldman gave a different explanation of the Vancouver arrangements. She testified that the appellant has a contract with a *transfer company* to pick up the mail from the Vancouver box and take it to Portland, where, as we have seen, both Mrs. Pautz and the appellant have their domiciles. The replies to the letters thus received are then carted back to Vancouver and mailed there, by "that same man that brings the letters."

When she was asked why this roundabout way of handling Mrs. Pautz's mail is employed, Mrs. Feldman repeatedly gave this cryptic reply: "Because it is convenient."

The handwritten letter of Mrs. Pautz was mimeographed and sent out directly from the appellants' laboratories without any notation or other disclosure to the addressee that it is being sent from the appellant's headquarters, or that the appellant has had it mimeographed. The envelopes in which the Pautz letters are sent out are addressed

in handwriting, although all the other correspondence of the appellant goes out in typed envelopes.

The evidence on this point makes it quite clear that it was the appellant's intention to have the recipients of the Pautz letters believe that Mrs. Pautz herself had written each individual letter and had mailed it at Vancouver.

After Mrs. Pautz's letter was sent out, the office of the appellant customarily mailed to those answering her advertisement a letter in which it was stated that Mr. and Mrs. Pautz usually have some Nue-Ovo "on hand and take it for a time every Spring as more or less of general tonic." This statement is in direct contradiction to Mrs. Pautz's testimony that she had not used Nue-Ovo since 1923 or 1924.

Both sides agree that "the question of good faith and the question of intent is not involved" in this case; that "the Government does not have to show a fraudulent intent on the part of the shipper or manufacturer;" and that, "conversely, if it is shown that the product proceeded against is adulterated or misbranded, then good faith or a lawful intent will not constitute a defense."

Prior to 1938, when the present Food, Drug, and Cosmetic law was enacted, the statute *did* provide that an untrue statement in the labeling of a drug product had to be "false and fraudulent" in order to render the product subject to condemnation for misbranding. Section 10 of the 1927 edition of 21 U. S. C. A. read in part as follows:

"§ 10. *Misbranded articles.* For the purposes of sections 1 to 15, inclusive, of this title, an article shall be deemed to be misbranded;

"Drugs. In case of drugs:

\* \* \* \*

"*False statement of curative or therapeutic effect.*—Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is *false and fraudulent.*" [Italics supplied]

The present law requires only that the labeling be "false or misleading in any particular" in order to bring the drug within the definition of "misbranded," 21 U. S. C. A. § 352 (a).

This does not mean, however, that under the present law the appellee, in presenting



to the jury a fair and complete picture of the claimant's activities, must sedulously avoid adducing any evidence of fraud. As the appellee points out—

"In the instant case, the jury had the right to know that whatever propensity the purchasers of Nue-Ovo might have had to analyze had been reduced to a minimum by the groundwork laid by appellant. In determining whether the labeling suggests to the user that Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, we submit that it was proper for the jury to consider the labeling representations in the light of the setting in which the manufacturer intended the user to read them."

It is well settled that the 1938 act was intended to make the provisions against misbranding stricter and not more lenient than they had been in pre-existing laws. The new statute was not designed to provide the misbrander of drugs with additional technical loopholes for escape, but to batten down those already existing.

The evidence of the Congressional intent, as construed by the Supreme Court of the United States, is impressive. In *United States v. Dotterweich*, 320 U. S. 277, 280-282, the court said:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [Cases cited] The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible rela-

tion to a public danger. [Case cited] And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . .' *United States v. Johnson*, 221 U. S. 488, 497-98.

\* \* \* \* \*

"\* \* \* Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906.' (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws,' but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1)"

Furthermore, the Act is remedial, and should be liberally construed so as to carry out its beneficent purposes. In *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, 442-443, the court said:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. *Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purposes of the act.*" [Italics supplied]<sup>3</sup>

We do not think that we would be construing the statute in accordance with the Congressional purposes if we were to hold that it was reversible error for the appellee to be allowed to introduce evidence regarding the "indirection" employed by the appellant in connection with the shuttling of

<sup>3</sup> See also *United States v. Dotterweich*, *supra*, 320 U. S. at page 282; *United States v. Antikamnia Co.*, 231 U. S. 654, 667; *United States v. John J. Fulton Co.* [CCA-9], 33 F. (2d) 506, 507; *United States v. 62 Packages, More or Less*, of

*Marmola Prescription Tablets* [DC Wis.], 48 F. Supp. 878, 887, affirmed, 142 F. (2d) 107, certiorari denied, 323 U. S. 731-732; 50 Am. Jur., Statutes, § 395, page 420.



the Pautz mail back and forth between Vancouver and Portland, Oregon. One would have to be quite naive not to discern in this subterfuge, the thinly disguised purpose of causing the public to believe that there was no connection between the appellant and Mrs. Pautz.

It is true that the letter was not part of the labeling. It was, however, part and parcel of the appellant's questionable promotional methods, some of which *were* reflected in the labels, as was amply disclosed by the evidence to which we have referred in the preceding section. It was not error for the court below to permit the appellee to lay before the jury the entire picture.

5. *There Was No Error in the Instruction Regarding the Test to be Applied in Determining Whether the Labeling Is Misleading*

The appellant complains that the "error" in the admission in evidence of the Pautz letter and advertisement, *supra*, was "compounded" when the court instructed the jury on 21 U. S. C. A. § 321 (n). That subsection reads as follows:

"(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

The objection is not that the instruction as to this subsection was erroneous *per se*, but that the error lay in giving *any* instruction as to that provision of the statute. The appellant contends that "the instant libels make no general charge of misbranding under which the appellee is entitled to rely upon Section 201 (n) of the Act, [21 U. S. C. A. § 321 (n)] *supra*," but that the present charge is "merely that the product *is not effective*." "Certainly," it is argued, "no reference to Section 201 (n) appears in any of the pleadings or the pre-trial order," etc.

In making this attack upon the court's instruction as to the subsection in question,

the appellant seems to forget the half-truths *in the labeling* to which we have referred in a preceding section herein. It will be remembered that, though the appellant announced in its label that its "Analysis of Ingredients" was based chiefly on the *United States Dispensatory*, the *Pharmacopoeia*, and various textbooks, and although it did indeed quote verbatim from some of these authorities, it unfairly omitted unfavorable comments regarding some of Nue-Ovo's ingredients.

It was to cover precisely such tricky omissions and suppressions that § 321 (n) was designed.

Furthermore, in *any* case where "an article is alleged to be misbranded because the labeling is misleading" in *any* respect, it is made mandatory by § 321 (n) itself that the jury "shall" take into account such omissions or suppressions. In the instant case, the third agreed issue in the pretrial order was "Whether or not the product is misbranded by reason of the labeling." In the libels themselves, it is set forth that the article "was misbranded . . . in that the statements . . . which appear in the labeling . . . are false and misleading in this," etc.

Accordingly, it was not only not erroneous for the court to instruct the jury on § 321 (n), but, under the facts of this case and under the terms of the subsection itself, it was the court's duty to do so.

6. *The Court Did Not Abuse Its Discretion in Refusing to Release the Product Under Bond*

Finally, the appellant asserts that, even if this court should hold "that the verdict may be construed as finding merely mislabeling consisting of the failure to disclose the difference of opinion among the experts" etc., then "fairness to appellant requires the release of the product under bond to permit amendment of the labeling and the [lower] court's denial of appellant's motion for that relief is an abuse of discretion," etc.

As we have tried to show, however, the appellee's evidence was not confined to "opinion among the experts," but was definitely *factual*.

In denying the application for the release of Nue-Ovo under bond, the court below said:

"[Nue-Ovo] hasn't any intrinsic value for food or for uses other than a medicinal use. The jury has determined



that it hasn't any value for that purpose, so it would be inconsistent, it seems to me, for me to hold that it should be preserved and released to the claimant."

It is well settled that the trial court, in a case of this kind, shall exercise its sound discretion as to whether the article shall be released under bond. *United States v. Two Cans of Oil of Sweet Birch, etc.* [DC N. Y.], 268 Fed. 866, 867; *United States v. 143 Packages, etc., of Nue-Ovo* [DC Wash.], 51 F. Supp. 1, 2; *United States v. 1322 Cans,*

*More or Less, of Black Raspberry Puree* [DC Ohio], 68 F. Supp. 881, 882.

After careful consideration of the 1100-page record in this case, we are convinced that the court below exercised its discretion soundly and judiciously. We believe that the interests of the public will be better subserved by having this product kept off of the market altogether.

The judgments are affirmed.

### 230 BOXES, MORE OR LESS, OF FISH, ET AL. (J. KOZLOFF FISH DISTRIBUTORS, CLAIM-ANT) v. UNITED STATES

United States Circuit Court of Appeals for the Sixth Circuit. No. 10624.

May 24, 1948. 168 F. 2d 361.

Seizure proceedings were instituted against fish infested with parasitic worms. The fish had been transported from Canada to Detroit, Michigan, and, before the filing of the libels, had been admitted into the United States and delivered to the consignee after being released by the Food and Drug Administration. While the fish were in the consignee's possession in Detroit, the Food and Drug Administration re-examined the fish and found them to be adulterated. Under Section 201 (b) of the Act, the shipments of fish were shipments in interstate commerce; commerce between a state and "any place outside thereof" includes imported articles of food.

Sections 201 (b), 304 (a), 402 (a), 801 (a), 801 (b), Federal Food, Drug, and Cosmetic Act.

The fish were adulterated by parasitic worm infestation when captured in the Canadian lakes; and when shipped into the United States were adulterated "when introduced into" and "while in" interstate commerce.

Sections 201 (b), 304 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

No logical reason was perceived for the assumption that sub-chapter VIII of the statute possesses superiority over the first seven sub-chapters; there is no inconsistency between Section 304 (a) and Section 801.

Sections 304 (a), 801 (a), 801 (b), 801 (d), Federal Food, Drug, and Cosmetic Act.

The reasonable interpretation would seem to be that Section 801 is designed to test the right to admission before an article may be brought into the United States, and that Section 304 (a) is operative after the article is released from Customs.

Sections 304 (a), 801 (a), 801 (b), Federal Food, Drug, and Cosmetic Act.

From a study of the legislative history of the Act, there is no justification for the argument that imports were not intended to be considered shipments in interstate commerce subject to seizure under Section 304 (a).

Sections 201 (b), 304 (a), 801 (a), 801 (b), Federal Food, Drug, and Cosmetic Act.



John C. Ray, Detroit, Mich., for appellant.

Leonard D. Hardy, Washington, D. C., and Joseph L. Bannigan, Detroit, Mich. (on brief: Leonard D. Hardy, Washington, D.C., T. Vincent Quinn, Washington, D.C., and Thomas P. Thornton, by Joseph L. Bannigan and Kenneth W. Smith, Detroit, Mich.), for appellee.

Before MARTIN, McALLISTER and MILLER, Circuit Judges.

MARTIN, Circuit Judge: The claimant, J. Kozloff Fish Distributors, has appealed from a decree of condemnation of fish, admittedly infested with parasitic worms, seized under libels of information filed in the United States District Court for the Eastern District of Michigan pursuant to section 334 (a), Title 21, U. S. C. A., of the Federal Food, Drug, and Cosmetic Act [June 25, 1938, c. 675, sec. 304, 52 Stat. 1044].

The articles of food seized were transported in four separate shipments from Winnipeg, Manitoba, Canada, to Detroit, Michigan; and, before the libels were filed, had been admitted into this country and delivered to the consignee at Detroit by the Bureau of Customs of the Treasury Department, after having been released by the Food and Drug Administration acting in accordance with section 381, Title 21, U. S. C. A., and the regulations promulgated thereunder.

*[Fish Found Adulterated Upon Reexamination]*

After the articles of food had been admitted into the United States and while in possession of the consignee or its agent at a warehouse in Detroit, the United States Customs Service rechecked the importations to ascertain whether the Tariff Laws of the United States had been complied with; and, after rechecking, took no proceedings in the matter to disturb the original entry. Simultaneously, however, the Food and Drug Administration, through inspectors, reexamined the fish and found them to be adulterated within the meaning of section 342 (a) (3), Title 21, U. S. C. A., in that the articles of food consisted wholly or partly of a filthy substance by reason of the presence therein of parasitic worms.

*[Fish Infested Prior to Shipment]*

Concededly, the infestation of the fish was not due to decomposition, or to any act of negligence of the claimant, but was caused by the presence of parasites in the

Canadian Lakes from which the fish were taken. It follows, therefore, that the fish were infested prior to their shipment from Winnipeg, Canada, to Detroit, Michigan. Parasital infestation in fish, not being visible externally, can be determined only by internal examination of the fish. The adulterated articles of food are now in the custody of the United States Marshal in their original unbroken packages.

*[Are Seizure and Condemnation Authorized]*

The foregoing findings of fact of the district court are in conformity with an agreed statement of the parties submitted in lieu of a record. The question which we must answer is whether, in the circumstances of the case, section 304 (a) of the Federal Food, Drug, and Cosmetic Act<sup>1</sup> [sec. 334 (a), Title 21, U. S. C. A.] authorized the seizure and condemnation of the articles of food.

*[Appellant's Contentions]*

The appellant contends that (1) the shipments of fish from Winnipeg, Manitoba, Canada, to Detroit, Michigan, were shipments in foreign and not in interstate commerce; (2) the fish were not adulterated in interstate commerce; (3) Customs entry of the fish with the approval of the Food and Drug Administration did not make the shipment interstate commerce within the meaning of U. S. C. A., Title 21, section 334 (a); and (4) the shipments, at the time of seizure, being still at the port of entry in the original containers continued to be "imports" within the meaning of section 381, Title 21, U. S. C. A.

*[Definition of "Interstate Commerce"]*

The plain words of the statute reject the first contention of appellant. Section 201 (b) of the Act thus defines interstate commerce:

"The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."

<sup>1</sup> Any article of food . . . that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate com-

merce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .



Section 321 (b), Title 21, U. S. C. A. [Italics supplied.]

No force is found in the argument that despite the words of the statute the definition should be restricted, as asserted by appellant, to the "traditional meaning of 'in spite of the words of the statute the definition the several states.'" If Congress intended to limit the coverage of "interstate commerce" exclusively to "commerce between the several states," why were the words "commerce between any State or Territory and any place outside thereof" written into the statute? No definition of any type of commerce other than interstate commerce is embraced in the Act. The term "foreign commerce" is not defined or used.

In some Acts of Congress, "interstate commerce" has been given a narrow definition: in others, a broad one. No uniform pattern is discernible, but each Act has been so drafted by the Congress as to accomplish the particular purpose desired. For examples of divergency, see National Fire Arms Act of June 26, 1934, U. S. C. A., Title 26, sec. 2733 (g), for narrow definition; and, for broad definitions, see Securities Act of 1933, U. S. C. A., Title 15, sec. 77B (7); Securities Exchange Act of 1934, U. S. C. A., Title 15, sec. 78C (17); Commodity Exchange Act, as amended in 1936, U. S. C. A., Title 7, sec. 2. The definition of "interstate commerce" in the last cited Act bears close similarity to that given in the Federal Food, Drug, and Cosmetic Act, in that the following language is employed:

"Commerce between any State, Territory or possession, or the District of Columbia, and any place outside thereof; . . ."

The argument of appellant receives no added weight by reference to the Federal Caustic Poison Act of 1927, U. S. C. A., Title 15, secs. 401, 402 (3) (c); The Filled Milk Act of 1923, U. S. C. A., Title 21, secs. 61, 62; The Meat Inspection Act of 1907, U. S. C. A., Title 21, sec. 71 *et seq.*; The Horse Meat Act of 1919, U. S. C. A., Title 21, sec. 96; The Virus, Serum, Toxin Act of July 1, 1902, U. S. C. A., Title 21, secs. 151-158; The Federal Insecticide, Fungicide and Rodenticide Act of June 25,

1947, U. S. C. A., Title 7, sec. 121 *et seq.* None of these statutes is inconsistent with an interpretation of the Federal Food, Drug, and Cosmetic Act as meaning that commerce between a State and "any place outside thereof" includes imported articles of food. The many different definitions of "interstate commerce" in Acts of Congress impel the conclusion that each definition must be received and applied in compliance with the language of the particular Act. See *Kirschbaum Co. v. Walling*, 316 U. S. 517, 520, 521; *Walling v. Jacksonville Paper Co.*, 317 U. S. 564, 569.

[*Fish Adulterated by Worm Infestation*]

We need scarcely pause to comment that there is no merit in the second contention of appellant that the infested fish shipped from Winnipeg to Detroit were not adulterated in "interstate commerce," as alleged in the libels. Indisputably, the fish were adulterated by parasitic worm infestation when they were captured in the Canadian Lakes; they were so adulterated "when introduced into" interstate commerce; and were, of course, infested "while in interstate commerce." They were, therefore, within the plain coverage of the Act. Cf. *Seven Cases of Eckman's Alterative v. United States of America*, 239 U. S. 510, 518.

[*Relationship between Sections 801 and 304(a)*]

The last two contentions of appellant intertwine and are appropriately discussed together. The basis of the argument seems to rest upon insistence that the provisions of sub-chapter *VIII*—Imports and Exports—U. S. C. A., Title 21, section 381, are "superior" to the first seven sub-chapters of the Act in relation to foreign commerce; and that the background of the existing Act of 1938 revealed in the Food and Drugs Act of 1906, taken with the legislative history of the existing enactment, supports an inference that Congress intended to provide special preference for "citizen importers" and "foreign exporters" by "excluding their commerce from the harshness of procedures provided against interstate commerce." It is urged that, while not entitled to posses-



sion of the articles of food for sale in the United States; claimant does have the right to export the fish to Canada, pursuant to the provisions of section 381.<sup>2</sup>

We perceive no logical reason, either from the provisions of the Act itself or from its legislative history, for the assumption that sub-chapter *VIII* possesses superiority over the first seven sub-chapters of the Act. Nor does there seem to be any inconsistency between the seizure provisions of section 334 (a) of Title 21, U. S. C. A., and the import-export provisions of section 801 [21 U. S. C. A., section 381], such as to preclude seizure of the shipments of fish in the lawful manner pursued in the instant case.

The Government concedes that section 801 [21 U. S. C. A., section 381] provides a special remedy, restricted to imports and exclusive for such time as the imported article remains in Customs' custody; but it is insisted here, and the district court so concluded, that the articles of food had been released from Customs' custody and were, thereupon, subject immediately to condemnation on libel of information pursuant to the provisions of U. S. C. A., Title 21, section 334. The Secretary of the Treasury, with the approval of the Federal Security Administrator, had unconditionally admitted the shipments into the United States. The reasonable interpretation would seem to be that section 801 is designed to test the right to admission before an article may be brought into the United States; and that section 334 (a) of Title 21, U. S. C. A., is operative after the article is released from Customs and admitted into this country. Cf. *United States v. Nine Barrels of Olives*, 179 Fed. 983 (D. C. Pa.).

From a study of the legislative history of the Federal Food, Drug, and Cosmetic Act, we find no justification for the argument that imports were not intended to be con-

sidered as shipments in interstate commerce. The Act of 1906, in U. S. C. A., Title 21, section 14, provided for seizure of an adulterated or misbranded article "if it be imported from a foreign country for sale." The present law does not contain this specific language; but provides, as heretofore stated, that the term "interstate commerce" means, *inter alia*, "commerce between any State or Territory and any place outside thereof" and, therefore, subjects an imported article to the condemnation procedure of U. S. C. A., Title 21, section 334 (a), as effectually as did the original Act. Obviously the Congress considered that no substantial change with respect to interstate commerce coverage was being wrought by the subsequent enactment of 1938. See S. Rep. No. 493, 73rd Cong., 2d Sess., page 19, accompanying S. 2800; S. Rep. No. 361, 74th Cong., 1st Sess., accompanying S. 5; H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4 [referring to the present section 334 (a) of Title 21, U. S. C. A.]. It should be observed that H. R. Rep. 2139, 75th Cong., 3d Sess., p. 13, expressly states that section 801 relates to imports and contains no substantial change from the provisions of the then existing law.

The legislative history does not support the insistence that citizen importers and foreign exporters were to be afforded any special privilege through restriction upon the seizure provisions of the Federal Food, Drug, and Cosmetic Act. Indeed, it is manifest that one of the main purposes in the repeal of the Act of 1906 and the substitution therefor of the Act of 1938 was to enlarge the protection of the public from adulterated foods. In the report of the Senate Committee on Commerce upon S. 5, a draft very similar to the bill as enacted, it was stated:

"This bill has been prepared with three basic principles in mind: First, it must

<sup>2</sup> The Secretary of the Treasury shall deliver to the Federal Security Administrator, upon his request, samples of food, . . . which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Federal Security Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that

(3) such article is adulterated, misbranded, or in violation of section 355, then such article shall be refused admission. . . . [21 U. S. C. A., sec. 381 (a)].

The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the

consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages. [21 U. S. C. A., section 381 (b).]



not weaken the existing law; second, it must strengthen and extend that law's protection of the consumer; and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest."

S. Rep. No. 91, 75th Cong., 1st Sess.

The Supreme Court of the United States has said:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

*United States v. Dotterweich*, 320 U. S. 277, 280.

An opinion of the United States Court of Customs and Patent Appeals announced January 7, 1947, while relating only to the recovery of customs' duties upon a shipment of fish from Canada to the United States, is of some interpretative significance here. Presiding Judge Garrett stated:

"We think section 558 of the Tariff Act of 1930, as amended by the Customs Administrative Act of 1938, and section 381 (a) and (b) [Sec. 801 (a) and (b) Fed-

eral Food, Drug, and Cosmetic Act] must, in cases such as this, be construed *pari passu* and that both must be given force and effect in determining whether there has been a release of merchandise from the 'custody of the government.'"

*United States v. W. F. Mackay*, 34 U. S. Court of Customs and Patent Appeals Reports 127, 133, 134.

After an imported article has passed from the control of the Customs officials and has been released and delivered to the consignee, no authority under federal law or customs' regulations is found to authorize the Secretary of the Treasury to seize such imports except in cases where fraud was involved in their entry, as for instance in *Origet v. United States*, 125 U. S. 240. Cf. *United States v. One Diamond Ring*, 2 F. (2d) 732. The instant case involves no issue of fraud in the importation of the adulterated food articles. The Secretary of the Treasury and the Federal Security Administrator had completed the performance of the duties imposed upon them by section 801 of the Act. When this point had been reached, the Food and Drug Administration took action by filing libels of information upon which the shipments of infested fish were seized where warehoused by the claimant. We conclude, as the district court did, that the articles of food so seized were subject to lawful condemnation in the manner pursued by due processes in conformity with the statute.

The decree of condemnation entered in the district court is, therefore, affirmed.

### UNITED STATES v. KENT FOOD CORP. AND CLARK-IGER FOOD PRODUCTS CO., INC.

United States Circuit Court of Appeals for the Second Circuit. Nos. 259 and 260. June 16, 1948. 163 F. 2d 632.

Certiorari denied, 335 U. S. 885 (1948).

See page 513.

Tomato catsup was condemned on the ground that it was adulterated in that it contained decomposed matter. The district court entered an order permitting release of the product to the claimants for export purposes. The district court did not have the discretion to resort, after the condemnation of a product under Section 304, to the special exemption granted by Section 801 (d) to commodities which are exported.

Sections 304 (a), 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

The power specifically given to a district court to do only specified things upon a condemnation of articles shipped in interstate commerce in violation of the Act excludes the possibility of according them a status they might ori-



ginally have had, had they never been introduced into interstate commerce for domestic sale.

Sections 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

There is nowhere disclosed in the Act an intention that a violator may avoid the consequences of his wrong by exporting the outlawed goods, after they have been condemned, to some foreign country.

Sections 304 (a), 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

The provisions of the decree appealed from, which provided for the release of the condemned product for export purposes, were beyond the power of the district court.

Sections 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

John T. Grigsby, Attorney, Department of Justice (J. Vincent Keogh, U. S. Attorney, and Morris K. Siegel, Assistant U. S. Attorney, both of Brooklyn, New York, and James B. Goding, Attorney, Federal Security Agency, on the brief), for appellant.

David Bergner, of New York City (Bergner & Bergner and Samuel H. Friedman, all of New York City, on the brief), for appellee.

Before SWAN, CLARK, and FRANK, Circuit Judges.

CLARK, District Judge: This appeal presents the question whether food condemned as adulterated in interstate commerce under the prohibition of the Federal Food, Drug, and Cosmetic Act, § 304, 21 U. S. C. A. § 334, may be released to the owners for export to another country. The district court, in an endeavor to conserve food available for human consumption and relying upon a provision of the Act exempting food products intended for export, § 801 (d), 21 U. S. C. A. § 381 (d), held in favor of the claimant owners. The United States has appealed, contending that such action is beyond the court's power.

*[Trial Court Permitted Release for Export]*

Here two libels were filed on February 26, 1947, for the seizure and condemnation of two lots of tomato catsup shipped in interstate commerce in November, 1946. Kent Food Corp. claimed the 215 cases involved in the first libel. It also claimed 441 of the 902 cases attached in the second libel, while Clark-Iger Food Products Co., Inc., claimed the remaining 461 cases. Claimants without answering moved "for an order approving a consent" to a decree of condemnation entered on condition that an order be made directing the United States Marshal to release the catsup to the owners and permit them to sell it for export purposes only. The district court accepted the claimants' contention that the catsup was packed for export when it was seized, stating that the adulteration consisted of high mold count, but that the goods were still fit for human

consumption. Accordingly it entered a decree containing first an order of condemnation of the articles to the United States of America and then successive orders providing for their release by the Marshal to the claimants upon the filing of a bond conditioned in appropriate detail for the packing of the articles for export and shipment out of the country, in compliance with the provisions of 21 U. S. C. A. § 381 (d) and under the supervision of the Food and Drug Administration of the Federal Security Agency. Thereupon the United States moved for a reargument, pointing out, among other things, that the Kent Food Corp. had actually been selling the adulterated articles for domestic consumption. The court granted the reargument and it adhered to its original ruling, even though it now found "that the claimants did not intend to export the goods, but planned to dispose of them in the domestic market." It held that it had power in its discretion to permit the export of the goods under proper restrictions and was not required to order them destroyed.

The appeal of the United States is based upon an asserted lack of power of the district court thus to dispose of condemned articles. In supporting its position, the Government also asserts that the court's holding has the effect of destroying the efficacy of the original order of condemnation, since it permits and encourages persons subject to the Act to gamble upon compliance, knowing that the penalty for violation will be only an order for sale



in the export trade. The only power of the Government to condemn is statutory, and hence our problem is solely one of statutory construction.

*[Statutory Power of the Government  
To Condemn]*

Subdivision (a) of 21 U. S. C. A. § 334 makes liable to condemnation any article of food "that is adulterated or misbranded when introduced into or while in interstate commerce." Subdivision (d) of the same section provides for the disposition of condemned food by "destruction or sale" as the court may direct, with the direction that it shall not be sold contrary to the provisions of the Act or the laws of the jurisdiction in which it is sold, and with the further proviso that, upon the claimants paying the costs and executing a bond conditioned that the article shall not be sold or disposed of contrary to the provisions of the Act or the laws of any state or territory in which sold, "the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Administrator." 21 U. S. C. A. § 342 (a) (3) states that a food shall be deemed to be adulterated "(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

*[Exemption of Food Intended for Export]*

In a separate chapter of the Act, dealing with imports and exports, it is provided that a food "intended for export shall not be deemed to be adulterated or misbranded under this chapter if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export." 21 U. S. C. A. § 381 (d). The section goes on to provide: "But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this chapter."

Thus the language of this last section deals with a subject matter entirely apart from that of condemnation under § 334. Here we have the statement of an *exemption* from the operation of the Act. Sec. 334 deals, however, with the consequences of a

violation of the Act by introducing an adulterated article into interstate commerce; and subd. (d) sets forth sanctions and remedies for such violation. Thus the part of the section which deals with release to the owner expressly provides either for destruction of the article or for its being brought into compliance with the provisions of the Act. It is further made clear that the article is not to be sold contrary to the provisions either of the Act or the laws of the jurisdiction in which it is sold. There is no provision for a sanction by way of a delayed exemption for export purposes, such as might have been secured had the articles been originally intended for such purposes. The district court did not consider that these articles were being brought into compliance with the law; indeed, there was no basis for such a view. The court thought it had discretion to resort, even after the articles had been condemned, to the special exemption granted by the statute.

*[Court Lacked Power To Release Food  
for Export]*

In this we think the court was in error. The power specifically given to the court to do only certain things upon condemnation of the articles excludes the possibility of according them a status they might originally have had, had they never been introduced into interstate commerce for the purpose of domestic sale. The clear purpose of the statute appears to be to visit the statutory penalties or sanctions upon articles thus found to be in violation of its provisions. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, 58; *United States v. Dotterweich*, 320 U. S. 277, 280. The practical aspects of the situation would seem to support this construction, for there is nowhere disclosed an intention that a violator of the Act may avoid the consequences of his wrong by then exporting the outlawed goods to some foreign country which will receive them. However laudatory may be the purpose to conserve the food supply (perhaps even of a condiment or relish such as catsup), an attempt to rewrite the Act along these lines seems likely to have the effect of nullifying its chief purposes. The several provisions for extensive remedies of not merely seizure and condemnation, § 304, 21 U.S.C.A. § 334, but criminal prosecution and injunction, §§ 301-303, 21 U. S. C. A. §§ 331-333, also suggest the impropriety of the result reach-



*U. S. v. Ninety-Nine Cases, etc., Peach Fountain Fruit, etc.*

ed below. Such limited legislative history as is called to our attention is to the same effect.<sup>1</sup>

Consequently we think that the provisions of the decree appealed from which go beyond the judgment of condemnation and provide for the release under the stated conditions of the articles to the

claimants for export abroad are beyond the power of the court. The libels must be remanded for the elimination of these provisions and for the substitution of provisions appropriate to the condemnation of the articles under 21 U. S. C. A. § 334 (d).

Reversed and remanded.

---

**UNITED STATES v. NINETY-NINE CASES, MORE OR  
LESS, EACH CONTAINING FOUR JARS OF AN  
ARTICLE LABELED IN PART "SOUTHLAND  
NET WEIGHT 14 OZS. PEACH FOUNTAIN  
FRUIT . . . ," ETC.**

United States District Court for the Eastern District of Tennessee,  
Southern Division. Civil No. 1030.  
September 10, 1948.

Seizure proceedings were instituted against peach and fountain fruit which did not conform to the standards prescribed by the Federal Security Administrator for preserves, and which were sold to wholesale groceries and retail stores labeled "Southland Peach Fountain Fruit (Delicious as a Spread)," etc. The name of the fruit appeared in large letters, and the words "Fountain Fruit" in small letters. Proof revealed that "Fountain Fruit" did not have a recognized meaning as a food product, and that the product had not been submitted to the trade in the past in containers comparable to those ordinarily used for preserves and jams. Proof also reflected that merchants bought the products with the idea that they were preserves, and that they were mixed upon shelves of retail stores with real preserves. On the basis of all the testimony and the labels and pictures of the products before the court, and considering the construction heretofore given to the word "purport," the court was of the opinion that the products did purport to be preserves.

Sections 304 (a), 402 (b), 403 (g), Federal Food, Drug, and Cosmetic Act.

The Act may be violated without any wrongful intent.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The court had the impression that a purchaser would buy the products thinking they were preserves, particularly when it was considered that the type of food involved had never been on the market for use as a spread or as a substitute for preserves.

Sections 304 (a), 402 (b), 403 (g), Federal Food, Drug, and Cosmetic Act.

Had the claimant plainly labeled the food by a true description, the label being in bold type and recommending it for use in place of preserves, there could have been no objection.

Sections 304 (a), 402 (b), 403 (g), Federal Food, Drug, and Cosmetic Act.

---

<sup>1</sup> The United States directs attention to congressional committee reports which emphasized the essential similarity of 21 U. S. C. A. § 381 (d) with the export exemption provision of the former § 2 of the Food and Drugs Act of 1906, 21 U. S. C. A. § 2, and argues that this imported an approval of the consistent policy, throughout the 32-year life of the Food and Drugs Act,

upon the part of the Administration to resist any attempt to effect the export of condemned food in the adulterated condition which was the basis of its condemnation. It cites *United States v. Jackson*, 280 U. S. 183, 193, and other cases, to the effect that an administrative interpretation, supported by reenactment of the statute, is entitled to weight in construing the statute.



Since the claimant had ceased the manufacture of the products, and in view of the facts involved, the claimant should be granted the privilege of taking the condemned products down under bond, to be disposed of under the supervision of the Food and Drug Administration.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

### Memorandum For The Judgment

#### [*Suit To Condemn Articles of Food*]

LESLIE R. DARR, District Judge: The suit seeks to condemn articles of food, under the provisions of 21 U. S. C. sec. 342 (b) (2) and 21 U. S. C. sec. 343 (g), upon the claim of adulteration and misbranding. The claimant made answer and denied these contentions.

#### [*Products Seized*]

The products seized were small fourteen ounce jars, which claimant sold to wholesale groceries and retail stores, and bore different labels as follows: "SOUTHLAND PEACH Fountain Fruit (Delicious as a Spread)," "SOUTHLAND PINEAPPLE Fountain Fruit (Delicious as a Spread)," and "TARA Fruit of the Good Earth PINEAPPLE Fountain Fruit."

#### [*Question for Determination*]

The parties have agreed that the products were introduced in commerce and that they did not come up to the required standard of preserves. Therefore, the single question for determination is whether the products purport to be, or are represented as, the standardized articles, peach and pineapple preserves, within the meaning of 21 U. S. C. sec. 343 (g).

#### [*Nature of "Fountain Fruit"*]

An examination of the jars shows that the labels contain the name of the fruit or tradename in large letters and the words "Fountain Fruit" are in small letters. The term "fountain fruit" does not have a recognized meaning as a food product. A product of this character has not been submitted to the trade in containers similar to the ones claimant used. So-called fountain fruit appears to have been generally put upon the market for family use in small containers of about six ounces and plainly labeled by such words as "Topping," "Sundaettes," etc., or this type product has been sold in large containers of a quart or more to confectioners and soda fountains for use in their business. The size jar used by the claimant is comparable to that ordinarily used for preserves and jams.

The proof reflects that the merchants bought these products with the idea that they were preserves, that they were mixed upon the shelves of the retail stores with real preserves, jams and jellies. So the libelant claims that this conduct amounted to a purporting of furnishing the products to the public as preserves. The claimant says that the products were plainly labeled "fountain fruit" and that there was no deception or imposition.

#### [*Definition of "Purport"*]

There are some cases defining the Congressional meaning of the word "purport" as used in this statute. *United States v. 306 Cases \* \* \* Tomato Catsup*, 55 F. Supp. 725; *Libby, McNeill v. United States*, 148 F. 2d 71.

#### [*Violation Without Wrongful Intent*]

Also, the statute may be violated without any wrongful intent. *United States v. 11¼ Dozen Packages, etc.*, 40 F. Supp. 208.

#### [*Products Purported to be Preserves*]

Considering this construction of the word "purport" and in view of all the testimony and considering that I have viewed the labels themselves together with the pictures of the products in stores, I am of the opinion that these products did purport to be preserves.

It must be remembered that the products were on sale during the time when there was a scarcity of sugar and the buying public was anxious to obtain sweets for family use. I have the impression that under all these conditions a housewife or other purchaser would buy these products thinking they were preserves, particularly when it is further considered that this type of food had never been on the market for table use as a spread or as a substitute for preserves.

#### [*No Objection to Truthful Labeling*]

This was, indeed, a new venture in trying out a table food, and had the claimant plainly labeled the food by true description, the label being in bold type, recommending it for use in place of preserves, jam or jelly, there could have been no objection.



*U.S. v. 116 Boxes "Arden Assorted Candy Drops"**[Proceedings for Condemnation  
To Be Sustained]*

For the reasons stated, however, I feel it my duty to sustain the proceedings for condemnation.

*[Manufacture Ceased When  
Proceedings Began]*

The claimant, so the proof discloses, ceased the manufacture of the products at the time these proceedings were begun and, as I understand, has no plans or desire to manufacture the products in the future.

*[Claimant To Take Over Condemned  
Products]*

In view of this and of the whole case, I direct that the claimant be granted the privilege, upon making proper bond, of taking over the condemned products, the same to be used and disposed of under the supervision of the Food and Drug Administration. If claimant elects not to retake the property, application will be made for disposition thereof in some other manner.

Proposed findings of fact and conclusions of law will be submitted.

Order accordingly.

**UNITED STATES v. 116 BOXES, MORE OR LESS, EACH  
CONTAINING 24 PACKAGES OF AN ARTICLE  
LABELED IN PART: (PKGS.) "ARDEN  
ASSORTED CANDY DROPS NET  
WEIGHT 1½ OUNCES  
\* \* \*, " ETC.**

United States District Court for the District of Massachusetts.  
Misc. Civil No. 7331. November 12, 1948. 80 F. Supp. 911.

Candy drops were seized on the ground that their containers, which had an average air space of 33 per cent, were "so made, formed or filled as to be misleading." The containers were packaged by a standard packaging machine which ordinarily filled each container with 17 drops; if the machine was set at 18 drops, the number of boxes which were overpacked and required to be discarded was between 5 per cent and 10 per cent of the total number of boxes filled. If an operator added drops by hand, he could often make the containers contain at least 20 drops. The court concluded that, as a matter of law, the shipment was not slack-filled.

Sections 304 (a), 403 (d), Federal Food, Drug, and Cosmetic Act.

The Act prohibits the shipment of a package of candy which is in fact so slack-filled as to be misleading even if the package correctly states the weight of the contents.

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

The question whether the package is misleading is a question of fact, and the standard is whether the container would be likely to mislead the ordinary purchaser of this type of merchandise, not one who was particularly attentive or prudent.

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

The court declared that it did not accept the argument that the question is whether the package is so filled as to mislead an average five-year-old child; that the test is what would be expected by an ordinary person who has been led to expect and desire machine-packing; that the expectation is that of a person who has that common degree of familiarity with our industrial civilization which furnishes the standard which Congress intended to be applied.

Section 403 (d), Federal Food, Drug, and Cosmetic Act.

William T. McCarthy, U. S. Attorney, Alfred G. Malagodi, Assistant U. S. Attorney, Boston, Mass., for plaintiff.

Joseph J. Gottlieb and Leonard Franklin, Boston, Mass., for claimant.



WYZANSKI, District Judge: This is a libel brought under the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 21 U. S. C. 301 *et seq.* for the condemnation of packages of confections manufactured and shipped in interstate commerce by Up-To-Date Candy Manufacturing Company. These packages contain either "Arden Assorted Candy Drops" or "Arden Root Beer Drops" or "Arden Lemon Drops" or "Arden Kandy Mints."

The libel charges misbranding within the meaning of 403 (d) of the Act, 21 U. S. C. 343 (d) which provides that "A food shall be deemed to be misbranded . . . if its container is so made, formed or filled as to be misleading."

It is conceded that the packages were shipped by the company in interstate commerce. The only question is whether there was misbranding within the statutory definition.

[*Statement of Facts*]

All the packages are substantially alike despite differences in the particular type of candy. All the types of candy are manufactured in a uniform size and style of lozenge. The company has changed the style over the years. In the packages seized, the style used is a slightly rounded rectangle which creates no peculiar packaging problem.

Each box measures in inches:  $3\frac{3}{4} \times 2\frac{1}{2} \times 1\frac{1}{4}$ . A box is intended to sell at retail at five cents. Each bears a legend stating the name of the drop and showing the weight of the box as  $1\frac{1}{2}$  ounces. And in fact all the boxes contained candy which weighed at least  $1\frac{1}{2}$  ounces. There is no statement as to the number of pieces of candy. Most of the boxes contain 17 pieces. Some, however, contain 18 or 19. When 17 pieces are in the box and a reasonable time has elapsed since manufacture, the candy settles so that there is an average air space in the box of 33%

[*Standard Packaging Machine Used*]

Each box in evidence was packaged by a standard packaging machine, manufactured by a third party, of the type used by a majority of leading concerns packaging candy or cough drops intended to retail at five or ten cents. Such a packaging machine is made with only slight variations necessary for each concern. The machine works in conjunction with a conveyor belt. The belt carries a flat piece of cardboard to the

machine, which folds it into a box with an opening left at one end. The machine then inserts wax paper, turns the folded box into an upright position and passes it under a rotary disk. Above this disk pieces of candy are placed. The disk has twenty apertures which may be plugged up to regulate the number of pieces which will drop into each box. Back of the place where the box stands under the disk is an agitator which jars the box during the time candy pieces are falling through the disk. This aids the candy to settle in the box so that more pieces can fall into the box. After being under the disk, the box moves to a finger-like contraption which folds over the wax paper and closes the box.

The process of manufacture is supervised by an operator who watches for spillage as the candy falls to the floor from the disk or the box. The operator discards boxes which are overpacked. He does not add drops by hand. If he were to do so, he could often make the box contain at least 20 drops of the present style. Without such additions by hand, it is admittedly practical to set the disk for at least 17 such drops. If the disk is set at 18 such drops, the machine occasionally jams. Moreover, at 18 drops the number of boxes which are overpacked and must be discarded is between 5% and 10% of the total number of boxes filled.

There was no evidence as to how many pieces of candy any consumer would expect to receive from a box of the type here involved.

[*Boxes of Candy Not Misbranded*]

Upon the basis of the foregoing facts and for the following reasons I conclude as a matter of law that the shipment did not violate § 403 (d) of the Act and that the libel should be dismissed without costs and the boxes delivered to the shipper.

The Act (which incidentally has not been interpreted by an official regulation or administrative pronouncement) prohibits the shipment of a package of candy which is in fact so slack-filled as to be misleading, even if the package correctly states the weight of the contents, *United States v. Cataldo*, 157 F. (2d) 802 (C. C. A. 1). The question whether the package is misleading is a question of fact. And the standard is not whether experts or men of peculiar training, experience, shrewdness or sophistication would be misled. Cf. *Federal Trade Com-*



*mission v. Standard Education Society*, 302 U.S. 112, 116. The standard is whether the container would be likely to mislead the ordinary purchaser of this type of merchandise, not one who was particularly attentive or prudent.

*[Expectations of the Ordinary Purchaser]*

But I do not go so far as to accept the argument, advanced by the Government, that the question is whether the package is so filled as to mislead an average five-year-old child who might expect the box to be filled to overflowing. Infantile anticipation is not the test. Rather it is what would be expected by an ordinary person—not necessarily an adult—who has been led to expect and desire machine-packing. Such a customer knows machine-packing is more sanitary than hand-packing. He knows it results in economies of mass production and that these economies are in some measure likely to be passed on to the ultimate consumer. Moreover, from buying various types of five-cent candies, cough drops and lozenges packed by machine in standard rectangular containers,

he has come to expect some slack or air space. Indeed, he recognizes that tight packing would often solidify into a mass pieces which he prefers to have separate. It is the expectations of a person who has that common degree of familiarity with our industrial civilization which furnish the standard which Congress intended to be applied. Congress had no intention to require abandonment of reasonably efficient methods of mass packaging by machine. See Senate Committee on Commerce, 73rd Cong., Report No. 493, p. 9; and Senate Committee on Commerce, 74th Cong. 1st Sess., Report No. 361, p. 9.

In the case at bar no evidence was introduced as to what an ordinary non-infantile purchaser would expect. But in my view he would not expect any particular number of lozenges. So long as he received ordinary lozenges not obviously so eccentric in shape as to result in peculiar packing difficulties, and so long as he received approximately as many of these lozenges as could conveniently be packed in a standard rectangular carton by machine, he would not in my opinion be misled.

---

UNITED STATES v. FRED URBETEIT, CLAIMANT OF 16  
ARTICLES OF DEVICE, MORE OR LESS, LABELED  
"SINUOTHERMIC," ETC.

United States Supreme Court, October term, 1948. No. 13. November 22, 1948.  
335 U.S. 355.

Reversing 164 F. 2d 245. See page 212.

See also pages 521 and 560.

Seizure proceedings were instituted against a device, "Sinuothermic," on the ground that it was misbranded in that accompanying leaflets contained false and misleading representations relative to the curative and therapeutic powers of the device in the diagnosis and treatment of disease. The leaflets were shipped at a different time than when the machines were forwarded, but described the alleged cures effected through the use of the machines, which bore only the words "U. S. Patent Sinuothermic Trade Mark." The Court held that it was the leaflets which explained the usefulness of the device and that, measured by functional standards, as Section 201 (m) (2) of the Act permits, the leaflets constituted one of the types of labeling which the Act condemns.

Sections 201 (m), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Section 304 (a) of the Act does not require the advertising matter to travel with the devices. The common sense of the matter is to view the interstate transaction in its entirety—the purpose of the advertising and its actual use.

Sections 201 (m), 304 (a), Federal Food, Drug, and Cosmetic Act.



The Court declared that it was plain that the movements of the machines and leaflets in interstate commerce were a single interrelated activity, not separate or isolated ones.

Sections 201(m), 304 (a), Federal Food, Drug, and Cosmetic Act.

The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics; the fact that the false literature leaves in a separate mail does not save the article from being condemned. Where, by functional standards, the two transactions are integrated, the requirements of Section 304 (a) are satisfied, though the mailings or shipments are at different times.

Sections 201 (m), 304 (a), Federal Food, Drug, and Cosmetic Act.

Mr. Justice DOUGLAS delivered the opinion of the Court: The United States filed a libel under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U. S. C. § 334), seeking seizure of 16 machines labeled "Sinuothermic." The libel alleged that the device was misbranded within the meaning of the Act (52 Stat. 1050, 21 U. S. C. § 352 (a)) in that representations in a leaflet entitled "The Road to Health" relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment and prevention of disease were false and misleading. It charged that the leaflet had accompanied the device in interstate commerce.

Respondent, Fred Urbeteit, appeared as claimant of several of the devices. He admitted that the devices and leaflets had been shipped in interstate commerce, but denied that they were shipped together or that they were related to each other. He also denied that the statements made in the leaflet were false or misleading. The case was tried without a jury and the articles were ordered condemned. The judgment was reversed by the Court of Appeals. 164 F. 2d 245. The case is here on certiorari to resolve the conflict between it and *Kordel v. United States*, ante, p. 345.

#### [The Facts]

Respondent Urbeteit terms himself a naturopathic physician and conducts the Sinuothermic Institute in Tampa, Florida. The machines against which the libel was filed are electrical devices allegedly aiding in the diagnosis and cure of various diseases and physical disorders such as cancer, diabetes, tuberculosis, arthritis, and paralysis. The alleged cures effected

through its use are described in the allegedly false and misleading leaflet, *The Road to Health*, published by Urbeteit and distributed for use with the machines.

Urbeteit shipped from Florida a number of these machines to one Kelsch, a former pupil of his who lives in Ohio. Kelsch used these machines in treating his patients and, though he did not receive them as a merchant, he sold some to patients. As part of this transaction Urbeteit contracted to furnish Kelsch with a supply of leaflets, which were sent from Florida to Ohio at a different time than when the machines were forwarded. Kelsch used the leaflets to explain the machines to his patients.

#### [Leaflets Used as Labeling]

The leaflets seem to have followed the shipment of the machines. But as *Kordel v. United States* holds, that is immaterial where the advertising matter that was sent was designed to serve and did in fact serve the purposes of labeling. This machine bore only the words, U.S. Patent Sinuothermic Trade Mark. It was the leaflets that explained the usefulness of the device in the diagnosis, treatment, and cure of various diseases. Measured by functional standards, as § 201 (m) (2) of the Act permits, these leaflets constituted one of the types of labeling which the Act condemns.

The power to condemn is contained in § 304 (a) and is confined to articles "adulterated or misbranded when introduced into or while in interstate commerce."<sup>1</sup> We do not, however, read that provision as requiring the advertising matter to travel with the machine. The reasons of policy which argue against that in the case of criminal prosecutions under § 303 are equally forc-

<sup>1</sup> The relevant portion of this section reads as follows:

"Any article of food, drug, device or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while

in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . ."



ible when we come to libels under § 304 (a). Moreover, the common sense of the matter is to view the interstate transaction in its entirety—the purpose of the advertising and its actual use. In this case it is plain to us that the movements of machines and leaflets in interstate commerce were a single interrelated activity, not separate or isolated ones. The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics. The fact that the false literature leaves in a separate mail does not save the article from being misbranded. Where by functional standards the two transactions are integrated, the requirements of § 304 (a) are satisfied, though the mailings or shipments are at different times.

[*Case Remanded to Court of Appeals*]

The Court of Appeals held that certain evidence tendered by Urbeteit as to the therapeutic or curative value of the machines had been erroneously excluded at the trial, a ruling that we are not inclined to

disturb. Petitioner claims, however, that the error was not prejudicial. The argument is that since the evidence of the false and misleading character of the advertising as respects the diagnostic capabilities of the machines was overwhelming, that false representation was adequate to sustain the condemnation, though it be assumed that the therapeutic phase of the case was not established. We do not reach that question. Since the case must be remanded to the Court of Appeals, that question and any others that have survived will be open for consideration by it.

*Reversed.*

Mr. Justice BLACK, Mr. Justice FRANKFURTER, Mr. Justice MURPHY, and Mr. Justice JACKSON dissent for the reasons stated in their dissent in *Kordel v. United States*, No. 30, decided this day, although this case arises under the limitation of 304 (a), “while in interstate commerce,” which has a different scope from 301 (k), while “held for sale after shipment in interstate commerce.”

---







# CRIMINAL CASES

## UNITED STATES v. NORMAN C. HERON (N. C. HERON CO.)

United States District Court for the Southern District of California. October 28, 1940. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 345) Issued March 1942.

The defendant was prosecuted for having introduced into interstate commerce a drug which was adulterated and misbranded. In instructing the jury, the district judge declared that experts, because of their special training or learning, are entitled to express opinions concerning the matters at issue, and that such testimony should be weighed precisely as the jury would weigh the testimony of any non-expert witnesses.

Sections 301 (a), 501 (b), 502 (a), Federal Food, Drug, and Cosmetic Act.

In instructing the jury, the district judge also declared that deception may result from the use of statements which are not technically false or which may be literally true, and that it is not difficult for one making and distributing drugs in interstate commerce to choose statements, designs, and devices which will not deceive.

Sections 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

### *[Instructions to Jury]*

HARRISON, District Judge: You have listened to counsel on both sides, and now you will have to listen to the court for a few moments as I read the instructions to you.

### *[Presumption of Innocence]*

By the filing of an information, no presumption whatsoever arises to indicate that a defendant is guilty, or that he has had any connection with, or responsibility for, the act charged against him. A defendant is presumed to be innocent at all stages of the proceedings until the evidence introduced on behalf of the Government shows him to be guilty beyond a reasonable doubt. And this rule applies to every material element of the offense charged. Mere suspicion will not authorize a conviction. A reasonable doubt is such a doubt as you may have in your minds when, after fairly and impartially considering all of the evidence, you do not feel satisfied to a moral certainty of the defendant's guilt. In order that the evidence submitted shall afford proof beyond a reasonable doubt, it must be such as you would be willing to act upon in the most important and vital matters relating to your own affairs.

### *[Reasonable Doubt]*

Reasonable doubt is not a mere possible or imaginary doubt or a bare conjecture; for it is difficult to prove a thing to an absolute certainty.

You are to consider the strong probabilities of the case. A conviction is justified only when such probabilities exclude all reasonable doubt as the same has been defined to you. Without it being restated or repeated, you are to understand that the requirement that a defendant's guilt be shown beyond a reasonable doubt is to be considered in connection with and as accompanying all the instructions that are given to you.

### *[Judging of the Evidence]*

In judging of the evidence, you are to give it a reasonable and fair construction, and you are not authorized, because of any feeling of sympathy or other bias, to apply a strained construction, one that is unreasonable, in order to justify a certain verdict when, were it not for such feeling or bias, you would reach a contrary conclusion. And whenever, after a careful consideration of all of the evidence, your minds are in that state where a conclusion of innocence is indicated equally with a conclusion of guilt, or there is a reasonable doubt as to whether the evidence is so balanced, the conclusion of innocence must be adopted.

### *[Credibility of Witnesses]*

You are the sole judges of the credibility and the weight which is to be given to the different witnesses who have testified upon this trial. A witness is presumed to speak the truth. This presumption, however, may be repelled by the manner in



which he testifies; by the character of his testimony, or by evidence affecting his character for truth, honesty, and integrity or his motives; or by contradictory evidence. In judging the credibility of the witnesses in this case, you may believe the whole or any part of the evidence of any witness, or may disbelieve the whole or any part of it, as may be dictated by your judgment as reasonable men. You should carefully scrutinize the testimony given, and in so doing consider all of the circumstances under which any witness has testified, his demeanor, his manner while on the stand, his intelligence, the relations which he bears to the Government or the defendant, the manner in which he might be affected by the verdict and the extent to which he is contradicted or corroborated by other evidence, if at all, and every matter that tends reasonably to shed light upon his credibility. If a witness is shown knowingly to have testified falsely on the trial touching any material matter, the jury should distrust his testimony in other particulars, and in that case you are at liberty to reject the whole of the witnesses' testimony.

There is nothing peculiarly different in the way a jury is to consider the proof in a criminal case from that by which men give their attention to any question depending upon evidence presented to them. You are expected to use your good sense, consider the evidence for the purposes only for which it has been admitted, and in the light of your knowledge of the natural tendencies and propensities of human beings, resolve the facts according to deliberate and cautious judgment; and while remembering that the defendant is entitled to any reasonable doubt that may remain in your minds, remember as well that if no such doubt remains the Government is entitled to a verdict. Jurors are expected to agree upon a verdict where they can conscientiously do so; you are expected to consult with one another in the jury room and any juror should not hesitate to abandon his own view when convinced that it is erroneous. In determining what your verdict shall be you are to consider only the evidence before you. Any testimony as to which an objection was sustained, and any testimony which was ordered stricken out, must be wholly left out of account and disregarded. The opinion of the judge as to the guilt or innocence, of a defendant, if directly or inferentially expressed in these instructions, or at any time during the

trial, is not binding upon the jury. For to the jury exclusively belongs the duty of determining the facts. The law you must accept from the court as correctly declared in these instructions.

Should you believe that Heron's Pure Eucalyptus Oil contains some ingredient which you believe to have a therapeutic or curative value in the treatment of the disease for which it is recommended, then there is no misbranding as to such disease.

*[Establishing Fact of Misbranding]*

You are charged that to establish the fact that Heron's Pure Eucalyptus Oil is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and as charged in the information, the Government must prove beyond a reasonable doubt:

That the labeling carries some statement regarding the contents of Heron's Pure Eucalyptus Oil which is false and misleading in some particular; and

That the statements made on the labeling regarding the curative or therapeutic effects of Heron's Pure Eucalyptus Oil are false and misleading; and

Such false and misleading labeling must be established by competent proof and by credible and convincing evidence.

*[Findings as to Product]*

You are instructed that, among other things, before you can find the defendant guilty of count I, you must find that Heron's Pure Eucalyptus Oil is a drug that is recognized in the United States Pharmacopoeia and that the strength of Heron's Pure Eucalyptus Oil differed from, and its quality and purity fell below, the standard set forth in the United States Pharmacopoeia in that Heron's Pure Eucalyptus Oil contained only 68 percent eucalyptol and that Heron's Pure Eucalyptus Oil is not soluble in 5 volumes of 70 percent alcohol; and should you so find as I have above instructed you, before you can find the defendant guilty you must find further that the fact that Heron's Pure Eucalyptus Oil contains but 68 percent eucalyptol and is not soluble in 5 volumes of 70 percent alcohol as the test prescribed by the United States Pharmacopoeia to test the strength, quality, and purity of Heron's Pure Eucalyptus Oil and unless you so find, you must find the defendant not guilty of count I.

If the evidence in this case, as to any particular count, is susceptible of two constructions or interpretations, each of which



appears to you to be reasonable, and one of which points to the guilt of the defendant, and the other to his innocence, it is your duty under the law to adopt that interpretation which will admit of the defendant's innocence, and reject that which points to his guilt.

You are further instructed that if any material claim or statement on either the label, carton, or circular is false or misleading then, regardless of the intent of the mind of the defendant, you are to find the defendant guilty.

You are instructed that it is against the law of the United States for any person to introduce or deliver for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

You are further instructed that a drug or device shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.

You are further instructed that the Pharmacopoeia of the United States, Volume XI, is an official compendium.

You are further instructed that a drug or device shall be deemed to be misbranded if its label is false or misleading in any particular.

*[Labeling]*

You are further instructed that the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

You are further instructed that if you find, from the evidence in this case, that Norman C. Heron did on or about November 21, 1939, deliver a package of Heron's Pure Eucalyptus Oil to an agent of the Railway Express Co. in Los Angeles, Calif., addressed to Nelson Drug Co. at Gooding, Idaho, and that said Railway Express Co. did send said package to Gooding, Idaho, you are to find that said package was introduced or delivered for introduction into interstate commerce.

You are further instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce,

a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., consigned to Nelson's Drug Store, Gooding, Idaho, that said eucalyptus oil fell below the standards required for oil of eucalyptus as set forth in the Pharmacopoeia of the United States, Volume XI, then you are to find the defendant Norman C. Heron guilty as charged in count I of the information.

You are instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., said package being consigned to Nelson's Drug Store, Gooding, Idaho; that in said packages were labels, cartons, and circulars containing false and misleading statements as to the curative and therapeutic efficacy of said Heron's Pure Eucalyptus Oil, then you are to find the defendant Norman C. Heron guilty as charged in count II of the information.

I have advised you that the defendant is charged with having violated certain provisions of what is known as the "Food and Drugs Act," the purpose of which was and is to protect consumers against impure and adulterated food and drugs, and also against the use of food or drugs which do not show what they contain by the brands on the packages; or which are misbranded or which contain misleading claims pertaining to the therapeutic and curative efficacy of the product. The prohibition of this act is directed only against the introduction into interstate commerce of any article of food, drink, or of any drug either adulterated or misbranded. In arriving at your decision in this case you are not concerned with the wisdom of this act of Congress in passing the Food and Drugs Act. You are only concerned with the facts in this case. You must determine what the facts are in relation to the issue which is formed by the information filed and the plea entered by the defendant.

*[Testimony of Experts]*

Ordinarily, in the trial of cases in court, witnesses are confined in their testimony to facts within their personal knowledge and they are not permitted to draw conclusions or express opinions. That is the general rule, but there is an exception to that rule where the points in issue arise out of a particular science or art concerning which there are trained minds who have special



knowledge, learning, or schooling in that particular field. Such persons are called experts and because of that special training or learning they are entitled to express opinions concerning the matters at issue. You will, of course, weigh and evaluate the testimony of the expert witnesses in this case precisely as you weigh the testimony of any nonexpert witnesses; that is to say, you will take into account the probability and reasonableness of the matters to which they have testified, the schooling of the person giving it, the learning that he has in his profession, or the want of it, and the breadth of his experience in the field which would enable him to arrive at a correct conclusion. In other words, his testimony should be given such weight as you believe it is entitled to receive.

*[Nature of Food and Drugs Act]*

Under the Federal Food and Drugs Act the term "drug" includes any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of mankind. The aim of the act is to prevent indirection and ambiguity in the labeling of drugs, as well as to prevent statements which are literally false. It is not difficult to choose statements, designs, or devices concerning the curative or therapeutic effect of an article of drugs which will not deceive. Those which are ambiguous and likely to mislead should be read favorably to the accomplishment of the purposes of the act and, if you find the labels used by the defendant, Norman C. Heron, describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, contain statements that are likely to mislead, you should find the defendant guilty of misbranding.

If you find that the circulars introduced in evidence in this case were contained in the packages admitted to have been shipped in interstate commerce by the defendant, and if you further find that said circulars contain statements describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, and if you further find that such statements are likely to mislead, you should find the defendant guilty of misbranding.

The Food and Drugs Act is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive and which are falsely and fraudulently made. Deception

may result from use of statements not technically false or which may be literally true. The law is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult for one making and distributing drugs in interstate commerce to choose statements, designs, and devices which will not deceive. That is his duty when engaged in such business. Too, statements which are ambiguous and likely to mislead should be read favorably to the accomplishment of the aims and purposes of the Food and Drugs Act.

This is important legislation intended to protect the people so far as this case is concerned from the transportation and sale of misbranded medicines, experience having shown that men and women afflicted with disease are disposed to try a professed remedy, no difference how useless or even harmful it may be if it is strongly recommended, and it is to protect the sick and afflicted and people who are easily imposed upon, from fraudulent practices of the unprincipled and avaricious that this law was passed. It is a wise law and in proper cases should be rigidly enforced.

If, after hearing the evidence in this case, you reach the conclusion that the drug or product known as "Heron's Pure Eucalyptus Oil" was harmless, that does not excuse the defendant, if you find that he placed statements upon said drugs which were false, concerning the curative and therapeutic effects of said products, as the danger and injury to the public from representations of this type is considerable in that it induces persons frequently to rely in serious cases upon preparations without healing virtue when, but for this reliance, they would no doubt secure proper advice and treatment for the ills which affect them.

If, in these instructions, any rule, direction, or idea be stated in varying ways, no emphasis thereon is intended by me, and none must be inferred by you. For that reason, you are not to single out any certain sentence, or any individual point or instruction, and ignore the others, but you are to consider all the instructions and as a whole, and to regard each in the light of all the others.

*[Admission of Evidence]*

At times throughout the trial the court has been called upon to pass on the question whether or not certain offered evidence might properly be admitted. With such



rulings and the reasons for them you are not to be concerned. Whether offered evidence is admissible is purely a question of law, and from a ruling on such a question you are not to draw any inference as to what weight should be given the evidence, or as to the credibility of a witness. In admitting evidence to which an objection is made, the court does not determine what weight should be given such evidence. As to any offer of evidence that was rejected by the court, you, of course, must not consider the same; as to any question to which an objection was sustained, you must not conjecture as to what the answer might have been or as to the reason for the objection.

You are instructed that if the judge has said or done anything which has suggested to you that he is inclined to favor the claims or position of either party, you will not suffer yourself to be influenced by any such suggestion.

I have not expressed, nor intended to express, nor have I intimated nor intended to intimate, any opinion as to what witnesses are, or are not, worthy of credence; what facts are, or are not, established; or what inferences should be drawn from the evidence adduced. If any expression of mine has seemed to indicate an opinion relating to any of these matters, I instruct you to disregard it.

*[Verdict To Be Rendered]*

The verdict to be rendered must represent the considered judgment of each juror.

In order to return a verdict it is necessary that each juror agree thereto. Your verdict must be unanimous.

When you retire to your jury room to deliberate, you will select one of your number as foreman and he will sign your verdict for you when it has been agreed upon. You will then return into court with the verdict and your foreman will represent you as your spokesman in the further conduct of this case in this court.

Forms of verdicts have been prepared for your convenience, and when you have agreed upon a verdict, the foreman will sign the verdict upon which you agree and return it into court.

Are there any exceptions on any of these instructions?

Mr. COTTER. No, your honor.

THE COURT. The clerk will now swear the officers to take charge of the jury.

(Whereupon the officers were duly sworn to take charge of the jury.)

THE COURT. The court will hand you the form of verdict, and you will now retire to the jury room for your deliberations.

Is it stipulated that the jury may have the exhibits?

Mr. COTTER. So stipulated.

Mr. LAW. So stipulated.

[The jury thereupon retired and after due deliberation returned a verdict of guilty. The court suspended the sentence on the first count for a period of 2 years, and sentenced the defendant to 6-months' imprisonment on the second count, which was also suspended for 2 years and the defendant was placed on probation for that period. The court also imposed a fine of \$300.]

## UNITED STATES v. COMMERCIAL CREAMERY CO.

United States District Court for the Eastern District of Washington,  
Northern Division. No. C-7382. March 12, 1942.  
43 F. Supp. 714.

The failure to afford the defendant an opportunity to present its views, under Section 305, does not prevent prosecution. The notice and hearing required in the section are administrative and not jurisdictional.

Section 305, Federal Food, Drug, and Cosmetic Act.

In a criminal prosecution under the Act, the burden of proving the allegations of the information beyond a reasonable doubt rests upon the Government, and the defendant is entitled to its recognized presumption of innocence.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.



But the rule of strict construction as to the statute itself has little or no application, since the statute is designed to prevent injury to the public health.

Title, Federal Food, Drug, and Cosmetic Act.

The statute is not indefinite or ambiguous. It is all inclusive, and prevents the shipment in interstate commerce of any food which contains any decomposed matter.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The use of the sense of smell as a medium of discovering the imperfections in food products is of such recent development as to make it doubtful whether it may be used as an exclusive standard by which the presumption of innocence may be overcome in a criminal case.

Sections 301 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

In a prosecution for shipping in interstate commerce frozen eggs alleged to be decomposed, the exclusive use of the organoleptic test was not sufficient to sustain the Government's burden of proving its case beyond a reasonable doubt.

Sections 301 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The rule that expert testimony is not conclusively binding upon a court applies in pure food and drug cases.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Lyle Keith, U. S. Attorney, Harvey Erickson and R. Max Etter, Assistant U. S. Attorneys, all of Spokane, Wash., for plaintiff.

Roy E. Lowe and J. Orville Humphries, both of Spokane, Wash., for defendant.

[*Nature of Proceedings*]

SCHWELLENBACH, District Judge: By information defendant is charged with introducing into interstate commerce in Spokane, Washington, for shipment to Portland, Oregon, two shipments of frozen eggs which consisted in whole or in part of a decomposed substance in violation of the Federal Food, Drug, and Cosmetic Act. The pertinent portions of the statute, grouped together for continuity purposes, read as follows (Title 21 U. S. C. A.):

Section 331:

"The following acts and the causing thereof are prohibited:

"(a) The introduction or delivery for introduction into interstate commerce of any food \* \* \* that is adulterated \* \* \*."

Section 333:

"(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor."

Section 342:

"A food shall be deemed to be adulterated—(a) (3) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

To the information a plea of not guilty was entered. By stipulation, a jury was waived

and the case presented to the court. By stipulation, the interstate character of the shipments and their identity was admitted by defendant.

[*Defendant's Contentions Answered*]

Defendant contends that the failure to afford to the defendant an opportunity to present its views as provided in the act (21 U. S. C. A. section 335) prevents this prosecution. This contention is without foundation. The notice and hearing required in Section 335 is administrative and not jurisdictional. *United States v. Morgan*, 222 U. S. 274; *United States v. American Laboratories*, 222 Fed. 104.

Defendant contends that the statute is too indefinite and that neither it nor the regulations promulgated under it establish standards sufficiently definite to enable the defendant to know of the crime with which it is charged and that any reasonable doubt as to the meaning of the statute must be construed in favor of the defendant. It is true that this is a criminal proceeding in which the burden of proving the allegations of the information beyond a reasonable doubt rests upon the Government and the defendant is entitled to its recognized presumption of innocence. *United States v.*



*U. S. v. Commercial Creamery Co.*

*Mayfield*, 177 Fed. 765; *Von Bremen v. United States*, 192 Fed. 904; *United States v. American Laboratories, supra*; *United States v. Newton Tea & Spice Co.*, 275 Fed. 394. But the rule of strict construction as to the statute itself has little or no application to the Federal Food, Drug, and Cosmetic Act designed, as it is, to prevent injury to the public health. *A. O. Andersen & Co., v. United States*, 284 Fed. 542; *United States v. 48 Dozen Packages, More or Less, of Gauze Bandage Labeled in Part Sterilized*, 94 Fed. (2) 641; *United States v. Research Laboratories, Incorporated*, 9th Circuit, No. 9898, decided Feb. 24, 1942; 126 Fed. (2d) 42. Furthermore, the statute is not indefinite or ambiguous. It makes illegal the introduction into interstate commerce of food which "consists in whole or in part of any filthy, putrid, or decomposed substance." (Emphasis is mine). This statute is all inclusive and prevents the shipment in interstate commerce of any food which contains any decomposed matter. Defendant urges that such a construction of the statute would result in unreasonable regulation and would prevent the shipment in interstate commerce of many foods not harmful to public health. If such a contention is sound, the argument in support thereof should be made to the Congress and not to the Courts. The act was passed by Congress under its authority to exclude from interstate commerce impure and adulterated foods and to prevent the facilities of commerce being used to enable such articles to be transported to the people who consume them and it is in the light of the purpose and of the power exerted by Congress that this act must be considered and construed. *Hipolite Egg Company v. United States*, 220 U. S. 45. Congress may itself determine the means appropriate to this purpose and, so long as they do no violence to other provisions of the Constitution, it is, itself, the judge of the means to be employed in exercising the powers conferred upon it in this respect. *McDermott v. Wisconsin*, 228 U. S. 115. Congress, following its own conception of public policy concerning the restrictions which may appropriately be imposed upon interstate commerce, is free to exclude from the commerce articles whose use it may conceive to be injurious to the public health, morals or welfare \* \* \*. The distinction on which the decision (*Hammer v. Dagenhart*) was rested, that Congressional power to prohibit interstate commerce is limited to articles which in themselves

have some harmful or deleterious property—a distinction which was novel when made and unsupported by any provision of the Constitution—has long since been abandoned. *United States v. Darby*, 312 U. S. 100.

## [Government's Testimony]

Plaintiff's testimony in this case consists of evidence submitted by three witnesses, all employees of the Food and Drug Administration. They were the inspector and assistant inspector at Portland, Oregon, who made the seizure, and the chief inspector at Seattle, who verified their findings. Their method of inspection consisted exclusively of the use of the organoleptic (affecting an organ or organs, especially those of touch, taste and smell. Funk and Wagnell's New Standard Dictionary, 1940 edition) test. In this case they used the sense of smell. In each instance, the witness testified that his training in the use of this test consisted of a three weeks course in California. While there they had made up for them "authentic packs" of various food substances using which they were taught to differentiate between the odor emanating from each. It will be noted that such packs were designated "authentic" rather than *proven*. For example, in making up an "authentic" egg pack, the eggs used were not submitted to any chemical or bacteriological test but were taken from what the witnesses described as "known" sources of either good or bad eggs and the odors were described to them as those which would come from either good or bad egg packs. The samples upon which plaintiff relies in this case were not subjected to either bacteriological or chemical tests nor was the method of inspection of the source used.

## [Defendant's Testimony]

Defendant's testimony included an explanation of the care used by it in the preparation of these shipments. It was uncontradicted that the eggs were carefully selected and examined by skilled candlers. They were broken in the approved fashion, using recognized methods by experienced breakers, into cups where they were judged as to appearance and smell by the breaking-room foreman who has had eleven years' experience. He testified that they were not decomposed. They were then churned and rushed to refrigeration. Plaintiff makes no contention about this breaking-room operation. The defendant also offered the testimony of a witness in Portland who was



present at the time of the seizure there by the Department's inspector. He, too, had had long experience in detection of odors of frozen eggs. He testified he could detect no odor of decomposition. Plaintiff also submitted the testimony of a witness now connected with the Washington State Department of Agriculture. He, likewise, had had many years of experience in the egg business. He testified that the organoleptic method of testing was more efficient if used at the time of breaking than if used later at the time of seizure.

[Facts Considered by Court in Determining Issue]

It is not the function of the Court in this case to make a choice for the Food and Drug Administration as to the method of testing to be followed by it. My problem is only to determine whether the Government has sustained the burden of establishing its case beyond a reasonable doubt. However, there are certain facts disclosed in the evidence and of which I have knowledge which I cannot overlook in deciding this case. They are:

1. That eggs have a peculiar propensity for the acquisition of odors from many and varied sources; for example, the food which the chicken eats, the place where the egg is laid, the place at which and the method used in storing the eggs, all have their effect upon the odor of the egg.

2. One of the most efficient methods of determining the presence or absence of decomposition in egg products comes from inspection at the source. The Department of Agriculture recognized this during the time that the Food and Drug Administration was a part of that Department. (Agricultural Year Book, 1924, pages 438 and 439). This was more specifically recognized by the Department in 1939. (Agricultural Year Book, 1939, p. 345).

3. The determination as to whether an egg contains decomposed substance is much more difficult than a similar determination as to most any other food product. As it was put by Allen in his work on *Commercial Organic Analysis by Chemists*, 5th ed., Vol. IX, p.557:

"A chemist who is called in to examine eggs or pass judgment on their quality must of necessity be an egg expert since their examination presents rather greater difficulties than other food products."

4. I do know that for years chemists have been seeking more efficient and rigid

methods for the determination of the presence of decomposition in eggs. One need only study the reports of the Association of Official Agricultural Chemists to become aware of this effort. (See Journal of the Association of Official Agricultural Chemists, Vol. XX, p. 159 (1937); Vol. XXI, p. 179 (1938); Vol. XXII, p. 298 (1939); Vol. XXIV, p. 119, (1941); Vol. XXIV, p. 319 (1941)). In most of these studies, representatives of the Food and Drug Administration participated either as referees or associate referees. It is difficult for me to believe that, if the organoleptic test is as efficient as plaintiff's witnesses say, that such complete and consistent efforts were being made by the chemists to acquire rapidity in their processes.

5. What is true of the chemists is also true of the bacteriologists. While their conclusions must necessarily be merely quantitative, nevertheless I doubt whether the American Public Health Association would have interested itself to the extent that it has in the bacteriological studies if plaintiff's contention as to the scientific efficiency of the organoleptic method is true. At least it may be said, as was said by the Committee on Microbiological Methods of Food Examination of the American Public Health Association, February, 1938,

"Criticism has been raised of the use of bacterial counts in the examination of food products on the grounds that it contributes nothing to our knowledge of quality and that organoleptic tests are equally reliable, less expensive and much more rapid. The development of bacterial standards for frozen eggs can be compared to the extensive efforts now being made to determine the exact physical and chemical properties that constitute good eggs. As the properties are understood, they will be interpreted in terms of appearance before the candle and candling must remain the practical means of examining interior egg quality. Thus, bacterial counts will serve as a basis for the establishment of the limit of quality of frozen eggs." (Journal, American Public Health Association. Vol. XXVIII, p. 56).

6. It must be conceded that the use of the sense of smell as a medium of discovering the imperfections in food products is of such recent development as to make it doubtful whether it may be used as an exclusive standard by which the presumption of innocence may be overcome in a criminal case. Dr. Eric Ponder, writing in the London scientific magazine *Discovery* for March, 1926, said this:



"The sense of smell is one of those little islands untouched by the advance of science, unclaimed for its proper use. We do not know how the olfactory organ functions. We know little about olfactory memory, we do not know enough about the potentialities of the sense to apply it usefully."

We do know that the olfactory nerves are just as efficient as the optic or auditory nerves. The difficulty lies in the fact that our conscious use of them is so less frequent. To put it another way, we may smell as frequently as we see or hear, but we do not sniff nearly as frequently as we look or listen. The problem is not one of sensitivity but rather of selectivity. Consequently, skill in the art of detection through the sense of smell comes from experience rather than aptitude.

*[Objection to Defendant's Expert Testimony]*

Counsel for plaintiff vigorously objected that I even permit the introduction of the testimony of the foreman of the defendant's egg-breaking plant with his eleven years' experience in the detection of odors in eggs. This, for the reason that he didn't have a college degree in science. The rule that expert testimony is not conclusively binding upon the Court applies in pure food and drug cases as well as any other case. *United States v. 17 Bottles, Large Size, and 65 Bottles, Small Size, More or Less, of an Article of Drugs Labeled in Part "B. & M."*, 55 Fed. (2) 264. Furthermore, I can see nothing in a three weeks' course of training in the organoleptic method, even when taken by men possessed of degrees of Master of Science and Doctor of Philosophy, which would justify me in arbitrarily accepting their testimony as against men who have had years of experience in the practical use of that very method. I do not suppose the foreman of the breaking plant, either when he was a candler or a smeller, ever dreamed that he was using the organoleptic procedure. That, however, did not prevent him

from developing the attribute of selectivity either in looking or smelling.

*[Government's Justification for Organoleptic Test]*

Plaintiff's chief inspector justifies the exclusive use of the organoleptic test on the ground that it is quicker and permits more territorial coverage than could be obtained by the combined use of this method with any one of the other three. I fully recognize the need for speed so far as the stoppage of shipments of decomposed food is concerned. Clearly, if the Administration's inspectors were compelled to wait until they have made either an inspection of the source or the chemical or bacteriological tests before making a seizure, public health might be endangered. I recognize that it is not likely that any one chemical method can be developed to detect and evaluate the spoilage in eggs in view of the limited, well-defined bio-chemical task of the microbial species. However, this is not merely a question of seizure. This is a criminal case in which the Government is confronted with the burden of proving its case beyond a reasonable doubt. The seizure in this case was made in January, 1941. The information was not filed until December 31, 1941. There was nothing to prevent the Government from having made certain as to the condition of these shipments by taking advantage of any one of the three additional tests.

*[Conclusion and Ruling]*

I am convinced from all of the testimony that the plaintiff has failed to sustain the burden that rests upon it in this case. To my mind, it has failed to overcome the presumption of innocence to which the defendant is entitled. Consequently, I must find that the defendant is not guilty of the violations charged in the two counts of the information and direct that this action must be dismissed.



UNITED STATES v. BUFFALO PHARMACAL CO., INC.,  
 AND J. H. DOTTERWEICH

United States Circuit Court of Appeals for the Second Circuit. No. 68.

December 3, 1942. 131 F. 2d 500.

Reversed, 320 U. S. 277. See page 278.

Intention to violate the Act is immaterial in a charge of misbranding.

Sections 301 (a), 303 (a), 303 (b), Federal Food, Drug, and Cosmetic Act.

While cross-examination had brought out the fact that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was evidence that the bottle in question had been properly cared for. The Court could not say that the evidence was insufficient to support the verdict of guilty.

Sections 201 (j), 201 (n), 501 (c), 502 (a), 502 (g), Federal Food, Drug, and Cosmetic Act.

The provision for notice and hearing in Section 305 is an administrative direction rather than a jurisdictional requirement for criminal proceedings.

Section 305, Federal Food, Drug, and Cosmetic Act.

Failure to convict the principal will not avoid the conviction of an agent who has committed all the elements of a crime.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

In the prosecution of a corporation and an officer for introducing into interstate commerce misbranded and adulterated drugs, it was held that Congress had not expected anyone except the principal to get a guaranty or to make the guilt of an agent depend upon whether his employer had gotten one.

Sections 301 (h), 303 (c), Federal Food, Drug, and Cosmetic Act.

In the prosecution of a corporate officer who had no personal connection with shipments made by the corporation, but who was in general charge of the corporation's business, it was held that the conviction could not stand and that the Act must be construed to mean that only the drug dealer, whether corporation or individual, is the "person" who causes the introduction into interstate commerce of contraband drugs.

Section 201 (e), Federal Food, Drug, and Cosmetic Act.

If an individual operated a corporation as his "*alter ego*" or agent, he might be held liable as the principal.

Section 201 (e), Federal Food, Drug, and Cosmetic Act.

Before: L. HAND, SWAN, and CHASE, Circuit Judges.

Robert J. Whissel; Samuel M. Fleischman, of counsel, for appellant.

George L. Grobe, U. S. Attorney; Robert M. Hitchcock, Assistant U. S. Attorney, of counsel, for appellee.

[*Facts of Case*]

SWAN, Circuit Judge: The appellant was prosecuted, together with Buffalo Pharmacal Company, Inc., a New York corporation of which he was general manager, for violations of section 301 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 331 (a). Three counts of the informations were submitted to the jury. The first count was based on an interstate shipment

on October 2, 1939 of a bottle of cascara compound which was charged to be misbranded, 21 U. S. C. A. § 352 (a); the other two counts related to an interstate shipment on January 9, 1940 of a bottle of digitalis tablets, one of the counts charging adulteration, 21 U. S. C. A. § 351 (c), and the other misbranding, 21 U. S. C. A. § 352 (a). Each of the shipments was made in filling an order received through the mails by Buf-



*U. S. v. Buffalo Pharmacal Co., Inc., et al.*

falo Pharmacal Company from a physician resident in a state other than New York. The corporation had purchased the drugs from a wholesale manufacturer; it repackaged them for the shipments under attack. The appellant Dotterweich had no personal connection with either shipment, but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians. The jury found him guilty on all three counts. For some unexplainable reason it disagreed as to the corporation's guilt. The sentence imposed on the appellant was a fine of \$500 on each count, with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.

*[Hinkle Pills Not Conforming to NF]*

The bottle of cascara compound carried a label reading "1000 Tablets Cascara Compound \* \* \* (Hinkle)," followed by a list of the ingredients, one of which was strychnine sulphate. The charge of misbranding was based on the fact that this ingredient had been removed from the formula for Hinkle pills stated in the official National Formulary<sup>1</sup> promulgated January 1, 1939. The issue left to the jury was whether the label was false and misleading in that it would lead the purchaser or the general public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills. Since intention to violate the statute is immaterial in a charge of misbranding,<sup>2</sup> we think the jury's finding that the label was false and misleading was not unsupported by the evidence.

*[Potency of Digitalis]*

The label on the bottle of digitalis tablets represented that each tablet possessed a potency of one U. S. P. unit of digitalis, whereas in fact analysis proved that the tablets were less than one-half of the represented potency. This was so far below the standard that findings of adulteration and

misbranding would seem to be inevitable, unless the deterioration occurred after the bottle of tablets was shipped. It was shipped on January 9, 1940 and its contents were analysed by government chemists in March 1940. While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding.

*[Lack of Notice to Appellant]*

Section 305 of the Act, set forth in the margin<sup>3</sup> provides that before the Administrator reports a violation to any United States attorney for prosecution, "the person against whom such proceeding is contemplated" shall be given notice and a hearing. In the case at bar such notice was addressed only to the corporation. In response thereto the appellant appeared on behalf of the corporation. He contends that a notice addressed to him personally was a condition precedent to his lawful prosecution. The district judge ruled that the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings. We agree with this conclusion. Such was the authoritative construction placed upon a similar provision in the Food and Drugs Act of 1906, 21 U. S. C. A. § 11. *United States v. Morgan*, 222 U. S. 274; see also *United States v. King & Howe*, 78 F. 2d 693, 696 (C. C. A. 2). In our opinion the changes in phraseology introduced by the 1938 Act are not such as to render obsolete these decisions. This appears quite clearly from the Congressional debates. 83 Cong. Rec. pp. 7792, 7794, 75th Cong., 3d sess. Articles by certain commentators are cited as expressing the opposite view,<sup>4</sup> but we are constrained to disagree with them.

<sup>1</sup> See 21 U. S. C. A. § 321 (j) and (n).

<sup>2</sup> See *Von Bremen v. United States*, 192 F. 904, 906 (C. C. A. 2), *Weeks v. United States*, 224 F. 64, 68 (C. C. A. 2) and *Strong, Cobb & Co. v. United States*, 103 F. 2d 671, 674 (C. C. A. 6) construing the Food and Drugs Act of 1906. That intention is not necessarily an element of the offense under the existing Act is made very clear by section 303, 21 U. S. C. A. § 333 (a) and (b) where different penalties are provided for simple violations and for violations "with intent to defraud or mislead."

<sup>3</sup> 21 U. S. C. A. § 335. Hearing before report of criminal violation. Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

<sup>4</sup> See "A Treatise on the Law of Food, Drugs and Cosmetics", 1942, p. 737; *Law & Contemporary Problems*, published by the School of Law of Duke University, 1939, Vol. 6, p. 74.



*[Acquittal of Corporation and Conviction  
of Manager]*

The appellant further urges that the jury's failure to convict the corporation is so inconsistent with the finding of guilt on the part of the appellant that the verdict against him cannot stand. Assuming that the statute includes within its prohibitions an agent who acts for his employer in shipping in interstate commerce misbranded or adulterated articles, the contention is without merit. No authority has been cited in support of the argument that failure to convict the principal will avoid the conviction of an agent who has committed all the elements of a crime. We think the usual principle is applicable that error cannot be asserted for inconsistency in the jury's verdict. See *Dunn v. United States*, 284 U. S. 390; *United States v. Pandolfi*, 110 F. 2d 736 (C. C. A. 2).

*[Liability of Employees]*

A more difficult question is presented by the appellant's contention that the statute is aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs. Section 301, 21 U. S. C. A. § 331, prohibits "the following acts and the causing thereof," namely, "(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Section 333 (a) of Title 21 declares that "any person" who violates any of the provisions of section 331 shall be guilty of a misdemeanor and on conviction be subject to imprisonment or fine or both. The Act defines the term "person" to include "individual, partnership, corporation and association." 21 U. S. C. A. § 321 (e). Who is the person causing "the introduction or delivery for introduction" into interstate commerce of a misbranded drug? Is the clerk who innocently packs or ships it guilty of the offense, as well as the employer for whom he works? While the statutory language seems literally to include all who have any part in causing delivery for introduction into interstate commerce, there are serious objections to so construing it. Subsection (c) of 21 U. S. C. A. § 333 provides

"No person shall be subject to the penalties of subsection (a) of this section \* \* \* for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the

name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in the case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded within the meaning of this chapter designating this chapter \* \* \*

Obviously such a guaranty, if given, will be obtained by the drug dealer, not by his clerk who may later deliver the article for shipment in interstate commerce; nor is such clerk literally within the protection of the quoted section, since he is not the one who "received" the article from the guarantor. It is difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one. The agent's guilt, like his principal's, must be independent of any scienter under section 331 (a). It would be extremely harsh to charge him criminally with the risks of the business as the drug dealer is himself charged. A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the "person" who causes the "introduction" or "delivery for introduction" of misbranded or adulterated drugs into commerce. In support of this conclusion the appellant adverts to the omission from the present Act of a provision which appeared in the 1906 Act in 21 U. S. C. A. § 4. This declared that in construing and enforcing the provisions of sections 1 to 15 of Title 21 "the act, omission, or failure of any officer, agent or other person acting for or employed by any corporation \* \* \* within the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation \* \* \* as well as that of the person." In our opinion the omission of this provision adds nothing to the argument already developed; it was doubtless omitted as unnecessary because it states an obvious general principle of agency.

The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant it must also apply to a shipping clerk or any menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be



*U. S. v. Harold Hain (Hain Pure Food Co.)*

understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his "alter ego" or agent he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue. Accordingly his conviction must be reversed.

The views above expressed in respect to the construction of the statute are those of a majority of the court. I am not in accord with them. I believe that the language of sections 331 (a) and 333 (a) is so inclusive as to render liable all persons who take part in causing a shipment in interstate commerce of misbranded or adulterated articles,

and that any insufficiency in the protection afforded an agent by section 333 (c) is not an adequate reason for limiting the statutory prohibitions to the dealer. The possibility that a literal interpretation of the statute may lead to the prosecution of insignificant agents rather than their employers is not, I believe, a serious risk and is a matter Congress was willing to leave to the good sense of prosecuting officials and trial juries. See *United States v. Buffalo Cold Storage Co.*, 179 F. 865, 867 (D. C. W. D. N. Y.), where a warehouseman who innocently shipped pursuant to instructions was convicted under the 1906 Act; see also the charge given by Judge Grubb in *United States v. Mayfield*, 177 F. 765 (D. C. Ala.).

[Conviction Reversed]

Judgment reversed.

## UNITED STATES v. HAROLD HAIN (HAIN PURE FOOD CO.)

United States District Court for the Southern District of California.  
April 15, 1943. Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944.

The defendant was prosecuted for having introduced into interstate commerce vitamin capsules which were adulterated and misbranded as a food and drug. Subsequent to the shipment, the defendant obtained a guaranty from the concern from which it had purchased the capsules assuring compliance with the Act of any vitamin products which might be sold to the defendant. Vitamins fall within the definition of a "drug" under the Act, and the counts referring to the product as a food were therefore unsupported by the facts and should be dismissed.

Sections 201 (f), 201 (g), 301 (a), Federal Food, Drug, and Cosmetic Act.

In order that the prosecution might make out a *prima facie* case, it was necessary to show only that defendant had violated the express requirements of the Act, since good faith did not enter into the matter.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The object of the guaranty provision of Section 303 (c) is to shift criminal responsibility rather than to absolve all parties therefrom.

Section 303 (c), Federal Food, Drug, and Cosmetic Act.

The language of the guaranty was susceptible of only one interpretation—that it was to be a "continuing guaranty," effective only from the date given, on into the future; its meaning did not include a guaranty of any sales made in the past.

Section 303 (c), Federal Food, Drug, and Cosmetic Act.



Federal Food, Drug, and Cosmetic Act  
*U S. v. Harold Hain (Hain Pure Food Co.)*

There was no showing that the signer of the guaranty had authority to bind the corporation; if he had signed it with his personal backing, it was fatal, because, under Regulation (g) under Section 303 (c), a guaranty, if signed by two or more persons, must state that such persons severally guarantee the article to which it applies.

Sections 201 (h), 303 (c), Federal Food, Drug, and Cosmetic Act.

[*Criminal Prosecution*]

JENNEY, District Judge: This is a criminal prosecution by the United States against Harold Hain, trading as the Hain Pure Food Company, for the violation of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Statutes at Large 1040).

The case is before the court under a stipulation of facts.

[*Shipment of Vitamin Capsules in Interstate Commerce*]

In essence, the facts are as follows:

The Defendant purchased a quantity of vitamin capsules from the International Vitamin Corporation of New York, which company manufactured, packaged, and labeled them. These were shipped to the defendant at his place of business in Los Angeles, in April 1939. Later, in June 1940, defendant obtained a guarantee from the International Vitamin Corporation assuring compliance with the Federal Food, Drug, and Cosmetic Act of any vitamin products they might sell to the defendant.

In October 1940, defendant sold and shipped a quantity of these vitamin capsules in interstate commerce.

[*Vitamin Potency Misrepresented on Labels*]

In November 1940, a sample was taken from this shipment, which was tested and analyzed by an agent of the Food and Drug Administration. The vitamin potency, in respect to vitamin B<sub>1</sub>, was found to be substantially below that represented on the labels of the boxes containing the capsules.

[*Failure of Defendant To Alter Labels or Contents*]

The defendant did not alter the contents of the vitamin capsules, the contents of the boxes, nor the labels on the boxes.

[*Charges Against Defendant in Four Counts*]

The information charges defendant with the violation of the Federal Food, Drug, and Cosmetic Act of 1938 (Hereafter called, the Act), in four counts.

The first count charges that the defendant delivered into interstate commerce an *adulterated food* in violation of the Act.

The third count charges that the defendant *misbranded a food* in violation of the Act.

The second count charges that the defendant delivered into interstate commerce an *adulterated drug* in violation of the Act.

The fourth count charges that the defendant *misbranded a drug* in violation of the Act.

These will be discussed in the order just stated.

[*Question as to Whether Vitamins Are Food or Drug*]

The apparent reason for drafting the information in four counts, and thereby presenting duplicate charges against the defendant—one based on a violation of the Act in respect to food, and the other in respect to drugs—is that there is a question as to whether concentrated vitamins in capsules are to be considered as a food or as a drug.

[*Disagreement Among Experts as to Classification of Concentrated Vitamins*]

The commercial use of concentrated vitamins in the fields of medicine and dietetics is a comparatively recent innovation. Experts in these fields disagree as to the category in which such vitamins are to be classed. However, it is not necessary for us to go into the subject extensively. Our inquiry is limited to the question of how vitamins should be classified solely in applying the provisions of the Act. In doing so, our first inquiry directs us to the definitions in the Act itself.

[*Definition of "Drug" as Contained in Act*]

In 21 U. S. C. A. 321 (g), it is stated:

"For the purposes of this chapter the term 'Drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the U. S., or official National Formulary, . . ."

[*Vitamins Listed in Pharmacopoeia of United States*]

The following vitamins are so recognized and listed in the Pharmacopoeia of the



*U S. v. Harold Hain (Hain Pure Food Co.)*

United States, 12th Revision, 1943: Vitamins A, B<sub>1</sub>, C, D, D<sub>2</sub>, D<sub>3</sub>, and G.

[*Vitamins Fall Within Definition of "Drugs"*]

It is seen, therefore, that vitamins fall within the definition of "drugs" insofar as the application of the Act is concerned. It is therefore immaterial in the determination of the case at bar how they are classified for other purposes.

[*Frank Case Supports Interpretation*]

This interpretation is supported by the case of *United States v. Frank*, 189 Fed. 195, (1911). Here the court in interpreting a section similar to ours in the 1906 Food and Drug Act states at page 199:

"Section 6 of the Act of 1906 provides: That the term 'drug' as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of diseases of either man or other animals . . . These are mere terms of description. If the Pharmacopoeia or National Formulary says something is a drug, it is a drug under the meaning of the Act. . . ."

[*Goodwin Case*]

The classification of vitamins as "drugs" is logical in the light of analogous cases. This is well exemplified by the case of *Goodwin v. United States* (C. C. A., 6th Circuit) 2 Fed. (2nd) 200, where the court held that mineral water transported, not being in its original state, and processes of separation of the constituent drug elements being carried to the extent that the commercial water can no longer be used as a beverage, but only in small quantities as a drug, it is to be classified as a "drug", and not a "food", within the Food and Drug Act.

[*Concentrated Vitamins Deemed Drugs*]

We shall therefore deem concentrated vitamins as "drugs" in the application of the Act before us.

[*Counts One and Three Unsupported by Facts*]

Since these vitamin products are "drugs", count one and count three of the information are unsupported by the facts.

[*Defendant Found Not Guilty as to Counts One and Three*]

Therefore, defendant is found not guilty as to counts one and three of the information.

[*Counts Two and Four Concerned with Unlawful Shipping of Adulterated and Misbranded Drugs*]

The allegations of violations of the Act in counts two and four, respectively, are concerned with the unlawful shipping of adulterated drugs in interstate commerce, and with the unlawful shipping of misbranded drugs in interstate commerce.

[*Good Faith Immaterial*]

In order that the prosecution may make out a prima facie case it is only necessary to show that defendant violated the express requirements of the Act. Good faith does not enter into the matter.

*Strong, Cobb and Co. v. United States*, 103 Fed. (2d) 671. Here it was held that in a prosecution for shipment in interstate commerce of adulterated cold tablets in violation of the Federal Food, Drug, and Cosmetic Act, *intent of defendant was not material*, since statute requires specific statements as to content of acetanilid compound.

In "*Law of Foods, Drugs, and Cosmetics*" by Toulman, 1942 Edition, it is stated on page 75:

"By the terms of the 1938 Act, good faith is a defence in criminal prosecution, when the charge is the *receiving* of adulterated or misbranded goods in interstate commerce. The good faith exemption does not apply when the charge is the *shipping* of misbranded or adulterated goods in interstate commerce. Therefore, intent, or something very like intent, must be proved by the government to secure a conviction when there is instituted a criminal prosecution for the receiving of adulterated or misbranded goods in interstate commerce. By implication, the new law *does not require intent to be proved* in cases where there is instituted a criminal prosecution for the *shipping* of adulterated or misbranded goods in interstate commerce."

[*Sections of Act Involved*]

The sections of the Food and Drug Act involved here are:

21 U. S. C. A. 331 (a), which states:

"The following acts and the causing thereof are hereby prohibited; (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

21 U. S. C. 351 (c), which states:

"A drug or device shall be deemed to be adulterated if it is not subject to the



provisions of paragraph (b) of this section and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess." 21 U. S. C. 352 (a), states:

"A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular."

It is readily seen that these statutes cover the stipulated facts in our case, and it is therefore unnecessary to repeat them.

Therefore, a prima facie case has been made out by the Government against the defendant on both counts.

However, the Act permits a defense to prosecution thereunder if a valid "guaranty" has been obtained.

This is set forth in 21 U. S. C. 333 (c), which states:

"No person shall be subject to the penalties of subsection (a) of this section (2) for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of section 331 (d), that such article is not an article which may not, under the provisions of section 344 or 355, be introduced into interstate commerce; . . ."

*[Delay in Obtaining Purported Guaranty]*

In our case a purported guaranty was obtained fourteen months after acquiring the product.

*[Validity of Guaranty To be Determined by Court]*

It is within the promise of the court to determine the legal meaning of documents.

In *United States v. Glaser, etc.* (C. C. A. 7) 224 Fed. 84, it was held that the question of whether or not a given instrument in writing is a guaranty is a question of law to be decided by the court.

Therefore, the question as to whether this guaranty is valid, as being within the foregoing section and therefore exempting the defendant from liability is a question of law for the court to determine from the document.

*[Object of Act]*

The object of this portion of the Act is to shift criminal responsibility rather than

to absolve all parties therefrom. The reason for this is that the primary purpose of the Act is the protection of the public. It is only secondarily concerned with the question of the identity of the person who is to bear the brunt of the burden—i. e. between the manufacturer and the retailer—so long as there is positive responsibility in some party. This interpretation is supported by *Steinhardt Bros. and Co. v. United States* (C. C. A. 2nd), 191 Federal 798, *United States v. Antikammia Co.*, 231 U. S. 654.

*[Mayfield Case]*

In *United States v. Mayfield, et al.*, 177 Fed. 765, the court in construing the counterpart of our section in the 1906 Food and Drug Act, states:

"The ninth section provides that no dealer shall be prosecuted under the provisions of the Act, when he can establish a guaranty, signed by the manufacturer from whom he purchased such articles, to the effect that the same article is not adulterated or misbranded within the meaning of the act; in which case, the manufacturer shall be amenable to the prosecutions, fines, and other penalties, which would otherwise attach to the dealer. The purpose of Congress was to place liability for the violation of the law upon some one in each instance. Primarily the liability is on the dealer who introduces the article into interstate commerce. The liability can be shifted from the dealer only by imposing the same liability upon the manufacturer. This can be done only by virtue of the manufacturer's guaranty to the dealer. If, for any reason, the guaranty is insufficient to impose liability upon the manufacturer, it remains where it primarily rested—upon the dealer. To have the effect of releasing the dealer from liability for the violation of the act, complained of in this prosecution, the guaranty must be of a character to impose liability for the same violation upon the manufacturer, if he were substituted for these defendants in this case; otherwise, both parties would escape liability, and the purpose expressed by Congress would be defeated. The act says that the manufacturer, who signs the guaranty shall be subject to the same prosecution and penalties as the dealer. If a conviction could not be sustained against the manufacturer upon its guaranty, if substituted for the defendants in this case, then the taking of the guaranty by defendants would be no defense to their violation of the law in reference to the shipment in question, though they had no knowledge that it was adulterated or misbranded."



*[Clear Compliance With Act Essential]*

Therefore, in order for the defendant to be absolved of liability he must comply clearly with the Act.

*[Guaranty]*

Here, Exhibit "A" is claimed by defendant to be such a guaranty.

The guaranty states that the International Vitamin Corporation guarantees that no food, drug, etc., "now or hereafter" made for defendant will "at the time of such shipment" be adulterated or misbranded within the meaning of the Act. Further on, it states that, "This guaranty shall be a continuing guaranty . . ."

This guaranty was given after the goods in question here were sold and delivered to the defendant.

In order for the guaranty to be valid as a defense, it must refer to the specific goods and the specific sale in question.

As stated in *United States v. Mayfield (supra)*,

"In order for the manufacturer's guaranty to be effective to impose any liability upon him for any violation of law as to the article, which is the basis of this prosecution, the guaranty must relate to the identical article introduced into interstate commerce by the defendants as dealers. Otherwise the answer of the manufacturer to the prosecution would be that he had never guaranteed the article shipped by the dealer, and the answer would be complete."

This is clearly not the case in this guaranty. The language is susceptible of only one interpretation—that the guaranty was to be a "continuing guaranty," effective only from the date given, on into the future. Its meaning clearly does not include a guaranty of any sales made in the past.

*[Interpretation of Postscript on Document]*

The apparent postscript on the document is claimed to have a retroactive effect, and to throw the guaranty within the purview of the exemption section.

The postscript reads, "The above guarantee applies to all merchandise shipped by us against your contracts." It is then signed by an unidentified "F. Satz."

This language may possibly be ambiguous. However, construed in the light of the guarantee, it becomes apparent that it is capable of only one meaning. That is, that the guaranty is a continuing guarantee.

However, assuming *arguendo*, that it meant all the defendant claims it means, it still would not help him. Two interpretations may be made of this postscript. One is that Satz is attempting to interpret the meaning of the guaranty; the other that Satz is attempting to supplement the legal liability of the corporation. The first view is of no effect here, because that is a question of law for the court to determine. The second view has no effect because there is no showing that Satz had authority to bind the corporation, or even that he was attempting to bind the corporation. Further, if he signed it with his personal backing, it is fatal because, as stated in Regulation (g) under U. S. C. 333 (c), "A guarantee or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies." This was not done here.

*[Guaranty Does Not Cover Capsules]*

Therefore, under any of the foregoing interpretations it is seen that there is no guaranty which would cover the goods in question.

*[Guaranty Fails To Exempt Defendant from Prosecution]*

Because of the foregoing, this guaranty fails in its validity for the purpose of exempting the defendant from prosecution, and in effect is as though no guaranty at all were given. This eliminates any defense defendant might have in this respect.

*[Defendant Found Guilty of Counts Two and Four]*

Defendant is found guilty of count two and count four as charged in the information.

*[Penalties for Such Violation]*

The penalties under this act are: (21 U. S. C. A. 333 (a), (b))

(1) Imprisonment for not more than one year, a fine of not more than \$1,000, or both, as for a misdemeanor.

(2) If the accused has already been convicted once, under that statute, the penalty is imprisonment for not more than 3 years, and a fine of not more than \$10,000, or both.

(3) If the violation is with intent to defraud and mislead, the penalty is the same as if the accused had already been once convicted.



EMPIRE OIL & GAS CORPORATION AND CHESTER  
WALKER COLGROVE, TRADING AS COLUSA  
PRODUCTS COMPANY v. UNITED STATESUnited States Circuit Court of Appeals for the Ninth Circuit.  
No. 10,189. June 28, 1943. 136 F. 2d 868.

The case involved a prosecution of the defendants for having introduced into interstate commerce drugs which were misbranded because of false claims as to their efficacy in the treatment of various diseases. The trial court was held to have committed error in refusing to permit a qualified witness to testify as to facts observed in clinical tests performed on animals by the witness and a veterinarian.

Sections 301 (a), 303 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The fact that a report prepared by a qualified witness contained matter as to which he could not testify should not have prevented its use to refresh the recollection of the witness as to his own acts in the testing of the defendant's remedies.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

No error was committed by the trial court in refusing to admit in evidence written testimonials of persons to prove the truthfulness of a claim by the defendants that the product was credited by others with producing remarkable results in treatment of acne, eczema, etc., since the Government had not offered proof upon that subject. Aside from that fact, the introduction of letters received through the mails could not be received, the whole subject being immaterial.

Sections 301 (a), 303 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Defendants' claim, that error had been committed because of the admission of the testimony of a witness for the Government that the product was an ordinary crude oil, was held to be without merit.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

Since error had been committed with respect to one count and a verdict of guilty returned, the Circuit Court of Appeals could not speculate as to whether the guilt was premised upon one or the other of the charges made by the Government.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

Walter M. Gleason and William B. Acton, San Francisco, Cal., for appellants.

Frank J. Hennessy, U. S. Attorney; A. J. Zirpoli, Assistant U. S. Attorney, San Francisco, Cal., for appellee.

Before: DENMAN, STEPHENS and HEALY, Circuit Judges.

[*Appeal from Conviction*]

STEPHENS, Circuit Judge: Empire Oil and Gas Corporation (a corporation) and Chester Walker Colgrove, trading as Colusa Products Company, were informed against in three separate counts charging the violation of the Act of Congress (June 25, 1938), known as the Federal Food, Drug, and Cosmetic Act [52 Statutes at Large, 1040, 21 U. S. C. A., §§ 331 (a), 352 (a)]. The corporation and Colgrove were tried by judge

and jury and were convicted upon all three counts. Judgments and sentence followed and both the corporation and Colgrove appeal therefrom.

[*Charges*]

It is charged in all three counts that packages containing drugs which were sent into interstate commerce were misbranded in that the branding falsely claimed the drugs were efficacious in the treatment of various named diseases.



In counts I and II the following skin diseases are specifically named: eczema, psoriasis, acne, ringworm, Athlete's Foot, burns, cuts, poison ivy and varicose ulcers. In count III the disease named is hemorrhoids or piles.

As to count III, an additional charge of misbranding is made that the labels on jars of ointment did not bear an accurate statement of the quantity of the contents in terms of weight and measure.

#### [Evidence]

The evidence establishes without conflict that the Empire Oil and Gas Corporation, with Chester Walker Colgrove as its president and active manager in immediate charge of the business, was conducting the business of producing and marketing products, the base of which came from a California oil well. As alleged in the information, appellants placed some of such products in the course of interstate commerce. The oil produced from the well is called Colusa Oil and is claimed by the producers and marketers to have remarkable remedial qualities. It is offered for sale as a liquid and as an ointment. The immediate containers of the products are labeled and packed in cartons or boxes which contain advertising matter related to the efficacy of the product as a remedy for a number of skin diseases and for hemorrhoids.

#### [Assignments of Error]

In their opening brief on appeal, appellants treat their assignments of error under six major points, and we shall treat them in their order of presentation therein.

#### [Sufficiency of Evidence]

It is claimed that the evidence is insufficient. There is no question but that there is great conflict upon the issue of misbranding as to the efficacy of the remedies. As will hereinafter appear, there was error committed which greatly affected the evidence upon this issue. As to count III, there is substantial evidence that the remedy containers went into interstate commerce without the required quantity of contents being printed upon the label [21 U.S.C.A., §§ 331 (a), 352 (a), 352 (b) (2)]. No error can be predicated upon this point.

#### [Testimony of Expert Erroneously Limited]

Appellants claim highly prejudicial error by reason of the trial court's rulings as to the testimony of Dr. C. E. Von Hoover.

Dr. Von Hoover was presented as an expert witness for the defense and his qualifying testimony revealed the following: Between 1922 and 1924 he attended New York Chemical College, now City College. There he spent eighteen months in the study of bio-chemistry and was awarded the Smedley D. Butler scholarship. (For convenience we quote definitions from Webster's New International Dictionary, Second Edition, of certain technical terms.)

*Biochemistry*: The chemistry of plant and animal life; biological, or physiological chemistry.

From 1924 to 1926 he attended Kings College in London, receiving therefrom the degree of Master of Science. While there he studied pharmacology and general science, including microbiology.

*Pharmacology*: 1. The science of drugs, including materia medica and therapeutics: 2. The materials of this science: the properties and phenomena of drugs especially with relation to their therapeutic value.

*Materia medica*: a. Material or substance of remedies. b. That branch of medical science which treats of the nature and properties of all the substances employed for the cure of diseases.

*Therapeutics*: That part of medical science which treats of the application of remedies for diseases; therapy.

*Therapy*: Treatment of disease.

*Microbiology*: The science or study of microbes.

He attended the University of Vienna two years under the Smedley D. Butler scholarship, receiving the degree of Doctor of Science. There he studied microbiology, laboratory pharmacology and general science and materia medica, with the use of the American pharmacopoeia. These subjects are the same as lead to a degree of M. D. The degree of M. D. also requires practice on patients. He is a professional dermatologist.

*Dermatology*: The science which treats of the skin, its structure, functions and diseases.

He was with Goodman Research Laboratory, New York, for a year on the clinical staff, testing pharmaceuticals and ointments and practicing general pharmaceutical chemistry. In collaboration with Medical Doctors and Doctors of Science he there tested the therapeutic value of and dangers of medicinal preparations to human patients.



In 1930 he established a clinical testing agency under his name at San Antonio, Texas, receiving business in that line of endeavor from high grade manufacturing chemists and especially from well-known firms manufacturing skin disease preparations. He has been so employed by Vitamin Research Company who manufacture synthetic vitamins. In his clinic a Medical Doctor diagnoses and prescribes. An assistant in the clinic is Dr. Beal, for some time United States Public Health Officer and surgeon. Another Medical Doctor assistant is a former Health Officer of San Antonio and past Trustee of the American Medical Society. Another assistant is Major Burby, retired Trustee of the American Veterinary Association, who acts as veterinary consultant in the handling of small animal practice and experimentation.

While Dr. Von Hoover was on the witness stand as a witness for the defendants, he was shown a report designated as Exhibit "L" for identification relating to the effect of Colusa Oil on dogs suffering from mange. He testified:

"It is my report. I prepared it; that is my report of the results of the application of Colusa Natural Oil to the skin of animals; associated with me was Dr. Burby, a veterinarian.—I am not a veterinarian."

Mr. Zirpoli, the assistant district attorney: "And this is a veterinarian's report?"

"A. You see my name on the other side as the laboratory man, \* \* \* the man that made the findings in the presence of the veterinarian. He couldn't make those tests because he is not qualified in bacteriology. \* \* \*

"Q. This report is predicated upon the experiments conducted upon the animal?"

"A. That is correct.

"Q. Made by Dr. Burby? A. And myself.

"Q. And Dr. Burby did the actual administration?"

"A. No, I administered to some dogs the application of oil in his presence.

"Q. This purports to be his conclusion as a veterinarian too does it not?"

"A. Canine dermatology is the practice of the veterinarian, and naturally, he would sign as the veterinarian, and I as the scientist, the micrologist."

Mr. Gleason, the attorney for defendants-appellants: "Q. I am going to ask you to refer to Defendants' Exhibit L

for identification and ask you if that document refreshes your recollection as to facts observed by you in these clinical tests on animals as to the therapeutic value and power of Colusa Natural Oil?"

"A. Yes.

"Q. Please state briefly the facts observed by you in these clinical tests on this animal therapy as to the results of the use of Colusa Natural Oil on skin diseases of animals. And, Doctor, confine yourself to the facts that you know of your own knowledge and do not read any of the opinions if they are opinions of Dr. Burby."

Mr. Zirpoli, the assistant district attorney: "I want to make this objection, your Honor. He is asked to testify as to the effect of the application of this oil, which calls for his opinion and conclusion as a veterinarian."

The Court: "Objection sustained."

(Exception noted.)

"Mr. Gleason: Q. Doctor, in the practice of your profession as a pharmacologist and your work for these firms that you mentioned yesterday, including the Goodman Laboratories and the rest of them, as their consultant, do you in the practice of your profession resort to animal therapy to test the efficacy of drugs and preparations?"

"A. Yes.

"Q. Is that a part of the ordinary practice of the ordinary pharmacologist?"

"A. That is the practice.

"Q. I will ask you to state, Doctor, the facts that you observed, in your clinical examinations; that is to say, this animal therapy, from the use of Colusa Natural Oil upon the skin diseases of dogs and cats used in this animal therapy."

Mr. Zirpoli, the assistant district attorney: "May it please the Court, I submit that the question is identical in different terms and objection is made exactly as it was made to the last question."

Mr. Doyle, attorney for defendant-appellant: "This question asks for the knowledge of the witness."

"The Court: The objection will be sustained."

It is apparent that the trial judge unduly limited the examination of the witness Dr. Von Hoover to the very great prejudice of the accused. The qualifications of Dr. Von Hoover were far more extensive than the average medical doctor or veterinarian possesses, and his familiarity with the materia medica, bacteriology, therapeutics, pharmacology and dermatology well qualified him to answer all of the questions which were put to him.



In regard to the report which he had prepared, it does not appear that he was asked to do otherwise than use it to refresh his recollection as to his own acts in the testing of the appellants' remedies. It is quite probable that the report contained matter as to which he could not testify, but this fact could not prevent its use in the limited manner suggested by appellants' counsel by their questions. There were other reports, some of them referring to experiments upon humans, which were similar in nature to the one above detailed, and their use by Dr. Von Hoover was prevented in like manner. This was error.

*[Refusal of Testimonials Immaterial]*

It is claimed that "The trial court committed prejudicial error in refusing to admit in evidence the testimonials offered by the defense." It appears in count I of the information, and is incorporated in the second count by reference (we do not here consider the legal effect of this practice), that advertising matter within the package contained the following recitation: "Colusa Natural Oil is credited by others with producing relatively as remarkable results as above pictured in relieving irritation of external Acne—Eczema—Psoriasis—Athlete's Foot or Ring Worm—Poison Ivy— \* \* \* Varicose Ulcers—Burns and Cuts."

It is claimed that defendants had a right to introduce written testimonials of many people to prove the truthfulness of this statement. It does not appear from defendants' recitation of the testimony that the government offered any proof upon this subject. This being true, there was no occasion for the truth to be established by the evidence. Aside from this, the introduction of letters received through the mail could not be received. The whole subject matter is immaterial.

*[Testimony Relative to Radium Immaterial]*

Under a single subhead appellants treat a number of assignments which we shall treat briefly.

Appellants think they were prejudiced by the court's refusal to permit proof going to the truth of a certain statement contained in the advertising matter regarding the action of radium. The government had introduced testimony along this line—probably to show that the preparations do not contain radium. Appellants admit, however, that they have never claimed and do not claim that the preparations contain radium.

In this circumstance any testimony relative to radium would be immaterial.

*[Testimony of Expert Witness for Government]*

Appellants complain that Dr. Tainter, an expert witness for the government, was permitted to testify as to the effect of Colusa Oil in poison oak cases and that Colusa Oil is an ordinary crude oil. This claim is without merit.

*[Impatience of Court Not Reversible Error]*

Appellants complain that the attitude of the court was prejudicial. The court evidenced some lack of patience, as we read the record, against both sides. No objections were interposed. We think the impatience exhibited was not of a degree sufficient to constitute reversible error.

*[Cross-Examination on Immaterial Matters]*

They also complain of the cross-examination on immaterial matters. This amounts to nothing.

*[Testimony as to Good Faith]*

In their brief under the subheading "The court erred in refusing to permit appellants to prove various facts to show their good faith," we have examined the claim and the argument and find no error.

*[Limitations on Testimony Inconsequential Error]*

Appellants complain that the testimony of a Mr. Everett and of a Mr. Baumgartner was unduly limited upon objections that the questions call for the witnesses' conclusions. We agree but think the error inconsequential in the circumstances. It appears that counsel for defendants voluntarily abandoned the subject.

*[Testimony That Public Was Not Misled]*

Appellants sought to show they were wrongfully prevented from showing that the public was not misled by their advertisements. There is nothing to the point.

*[Count Not Duplicious]*

Appellants claim that the third count is bad as being duplicious. Upon authority of *Weeks v. United States*, 445 U. S. 618, and *United States v. Swift*, 188 Fed. 92, we hold that the third count of the information is not duplicious. In the latter cited case it is said, "Duplicity in an indictment means the charging of more than one offense, not the charging of a single offense committed in



more than one way. Duplicity may be applied only to the result charged, and not to the method of its attainment."

*[Necessity of Intent Not Passed Upon]*

The government insists that there is substantial, even conclusive, evidence to support the conclusion that each package of drugs referred to in count III did not bear an accurate statement of the quantity of the contents in terms of weight or measure and that the verdict must stand as to this count upon the evidence alone. But the issue of guilt or innocence upon each separate count was submitted to the jury upon all of the material evidence relevant to each count. We have seen that reversible error was committed in the admission of evidence relative and material to count III and a verdict of guilty was returned. In these circumstances we cannot speculate as to whether the guilt was premised upon one

or the other or upon all of the allegations contained in this count. Evidence was offered by appellants to show that any failure upon their parts to properly designate the amount of contents on labels used as charged in count III was accidental or by mistake of another. Upon objection that the evidence was immaterial, the court denied its reception.

The instructions to the jury are in accord with the government's contention that no intent is necessary to a conviction upon the applicable statute and that no explanation of accident or mistake in any way affects the guilt or innocence of the accused. This subject is inadequately treated in the briefs, and since the judgments must be reversed upon the errors occurring during the examination of Dr. Von Hoover, we do not pass upon it.

Reversed.

## UNITED STATES v. HOWARD-IOWA PRODUCTS CO.

United States District Court for the Southern District of Iowa. October 13, 1943. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1010)  
Issued March 1945.

Prosecution was instituted against the defendant for having introduced into interstate commerce a worm powder for which false therapeutic claims had been made. It was held that the drug was labeled and referred to as a worm powder for Ascaris worms, that nothing in the label or circular enclosed with the package suggested that the product was efficacious in the cure or mitigation of all worms in hogs, and that a demurrer to the court making that charge of misbranding should be sustained.

Sections 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

*[Demurrer to Information]*

DEWEY, District Judge: To an Amended and Substituted Information the defendant has filed a demurrer to Count 1, in effect, claiming that such count does not charge an offense against it.

The charge is misbranding of drugs.

*[Drug Labeling]*

The drugs complained of are labeled "IOWA WORM POWDER FOR ASCARIS WORMS IN HOGS" and this statement appears on the outside of the package.

Accompanying the package and inside thereof is a circular directing the use of the worm powder on hogs. The circular in its

direction for use refers to "the Worm Powder" as being "the Iowa Worm Powder" and it is difficult to see how it refers to any other powder than that stated on the package as being "Worm Powder for Ascaris Worms in Hogs."

*[Charge that Labeling Is False and Misleading]*

The charge in Count 1 is that the label on the outside of the package showing two hogs, one thin and unthrifty and the other fat and thrifty looking, with the statement thereunder: "Take Iowa Worm Powder and be Fat," together with the directions for the use of the powder contained in the package, which does not specifically refer to Ascaris Worms in hogs, but only to "the



Worm Powder" and to the "Iowa Worm Powder," is false and misleading in this: "that the said statements represented and suggested that said drug would be efficacious in the cure, mitigation, treatment or prevention of all species of worms that infest hogs."

Specifically, then, the charge is that the label on the outside of the package, together with the directions for the use of the worm powder, by suggestion and inference, states and represents that the worm powder would be efficacious in the cure of all worms that infest hogs instead of Ascaris Worms alone.

*[Circular Constitutes Labeling]*

The court raised the question as to whether the circular enclosed in a package should be considered on the question of misbranding, but the statement in the new act of 1938 that "the term 'labeling' means all labels and other written, printed, or graphic matter \* \* \* accompanying such article," and the case of *Eckman's Alterative v. United States*, 239 U. S. 510, definitely determine that the circular contained within the package is to be considered on the question of whether the labeling was a misbranding.

*[No Representation that Product Would Destroy All Worms]*

However, I am unable to find anything in the label or in the statement enclosed in the package that indicates, let alone,

suggests or states, that the Iowa Worm Powder in the package was efficacious in the cure or mitigation of all worms in hogs.

The label in large type expressly states that it is "Worm Powder for Ascaris Worms in Hogs" and designates it as "Iowa Worm Powder." The directions for the use of the powder refer to either "the Worm Powder," which certainly means the Worm Powder contained in the package, or "Iowa Worm Powder," which even more definitely refers to the Worm Powder in the package, and the worm powder in the package is labeled as clearly and distinctly as it could be as a Worm Powder for Ascaris Worms without any suggestion or inference that it could be used or was efficacious in any manner or degree in destroying other worms in hogs.

*[Demurrer Sustained and Count Dismissed]*

The defendant's demurrer to Count 1 of the Amended and Substituted Information is sustained and said Count is dismissed as not stating an offense against the defendant. The United States of America excepts. Signed at Des Moines, Iowa, this 13th day of October, 1943.

[On November 30, 1943, no appeal having been noted with respect to the ruling on the demurrer, the court imposed a fine of \$100 on each of counts 2 and 3, a total of \$200, together with costs.]

---

UNITED STATES v. GREENBAUM

United States Circuit Court for the Third Circuit. No. 8350. October Term, 1942. Decided October 25, 1943. 138 F. 2d 437, 152 A.L.R. 751.

The constitutional requirement of due process is not violated merely because *mens rea* is not a required element of a prescribed crime.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Where the offences prohibited and made punishable are capable of inflicting widespread injury, and where the requirement of proof of the offender's guilty knowledge and wrongful intent would render enforcement of the prohibition difficult, if not impossible, the legislative intent to dispense with *mens rea* as an element of the offense has justifiable basis. Notable among such offences are dealings in adulterated foods and drugs.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The requirement of Section 305 that, before criminal prosecution for a violation of the statute may be instituted, the person against whom such proceeding is contemplated shall be given an opportunity by the Administrator to present his views with regard to such contemplated proceeding, nega-



tives any idea that proof of guilty knowledge and wrongful intent at trial of an offense under the Act is necessarily implicit.

Section 305, Federal Food, Drug, and Cosmetic Act.

The language of Section 303 (b), as compared with the language of 303 (a), does not require an implication that, under the latter section, proof of the alleged offender's knowledge and wilfulness was not intended.

Sections 303, (a), 303 (b), Federal Food, Drug, and Cosmetic Act.

The court could perceive an intent in Section 303 (a) to punish persons who introduce adulterated foods into interstate commerce regardless of their lack of knowledge or wilfulness.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

Frederic M. P. Pearse, Newark, N. J., for appellant.

Vincent E. Hull, Asst. U. S. Atty., Newark, N. J., for appellee.

Before BIGGS, JONES, and DOBIE, Circuit Judges.

[Facts of Case]

BIGGS, Circuit Judge: An information was filed against the appellant, Samuel Greenbaum, president of The Bakery Mart of Newark, Inc., and against that company, charging him and it, in two counts, with unlawfully introducing and delivering for introduction in interstate commerce cans of adulterated (i. e., rotten) eggs. The pertinent statutory provisions are set out below.<sup>1</sup> At the close of the case a motion was made on behalf of both defendants to dismiss the information and for a directed verdict on the grounds that the information did not charge a crime and that the proofs offered were insufficient to sustain a conviction. The motion was denied. The appellant and the company were found guilty on both counts. Greenbaum was sentenced to pay a fine of \$300 and to three months imprisonment. He has appealed.

<sup>1</sup> See the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. as follows:

Section 331, "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

Section 342, "A food shall be deemed to be adulterated—(a) (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;"

Section 321, "(f) The term 'food' means (1) articles used for food or drink for man or other animals."

Section 333, "(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine,

The information did not charge that he knew that the eggs were rotten when he shipped them into interstate commerce. No proof was offered of guilty knowledge on his part. He contends that for these reasons the judgment should be reversed.

[Guilty Knowledge Not Necessary To Sustain Conviction]

Whether allegation and proof of *mens rea* is requisite to a conviction for a crime which carries with it a possible sentence to penal servitude depends upon the legislative intent evidenced by the statute which defines and punishes the particular offense. *United States v. Balint*, 258 U. S. 250, 252. The constitutional requirement of due process is not violated merely because *mens rea* is not a required element of a prescribed crime. *Shevlin-Carpenter Co. v. Minnesota*, 218 U. S. 57, 69, 70; *United States v. Balint*, *supra*, at p. 252.

"(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 331, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

"(c) No person shall be subject to the penalties of subsection (a) of this section, (2) for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter . . ."

Section 335, "Before any violation of this chapter is reported by the administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."



While the absence of any requirement of *mens rea* is usually met with in statutes punishing minor or police offenses (for which fines, at least in the first instance, are ordinarily the penalties) we think that interpretation of legislative intent as dispensing with the knowledge and wilfulness as elements of specified crimes is not to be restricted to offenses differentiable upon their relative lack of turpitude. Where the offenses prohibited and made punishable are capable of inflicting widespread injury, and where the requirement of proof of the offender's guilty knowledge and wrongful intent would render enforcement of the prohibition difficult if not impossible (i. e., in effect tend to nullify the statute), the legislative intent to dispense with *mens rea* as an element of the offense has justifiable basis. Notable among such offenses are dealings in adulterated foods and drugs. Cf. *United States v. Balint*, *supra*, pp. 252-253; see also Public Welfare Offenses, Sayre, 33 Columbia Law Rev., 55, 70, *et seq.*, and Ignorance and Mistake in Criminal Law, Perkins, 88 Univ. of Pa., 35, 38, *et seq.*

The statute under which the appellant was indicted, convicted and sentenced, makes no specific requirement of allegation or proof of the offender's knowledge and wilfulness. While the failure so to provide does not necessarily determine that guilt of the offense may be established without such allegation and proof,<sup>2</sup> we conclude that the requirement of § 335, that, before criminal prosecution for a violation of the statute may be instituted, the person against whom such proceeding is contemplated shall be given an opportunity by the Administrator to present his views with regard to such contemplated proceeding,<sup>3</sup> negatives any idea that proof of guilty knowledge and wrongful intent at trial of an offense under § 333 (a) is necessarily implicit. The prescribed inquiry, a preliminary requisite to prosecution, is designed to search out the possible innocent mind of the particular offender by establishing before trial, his good faith or the extent of his actual knowledge and wilfulness.

We cannot agree with the contention of the government that the fact that an offense under § 333 (b), which deals with the introduction of a prohibited article in interstate

commerce "with intent to defraud or mislead," is more severely punished than the first offense under § 333 (a) furnishes an implication that under § 333 (a), proof of the alleged offender's knowledge and wilfulness is not intended. If "intent to defraud or mislead" embraced all instances where there was knowledge or wilfulness, then the argument, based on the inclusion of the requirement in the one instance and its exclusion in the other, would be both pertinent and cogent. But, conceivably, there can be instances where the introduction of a prohibited article in interstate commerce is with knowledge and wilfulness and yet without intent to deceive or mislead, e.g., where the consignee of the shipment knows what he is getting and gets what he wants. Hence, the alleged distinction seems possibly to contain the reverse implication.

Also, it must be conceded that the case of *Baender v. Barnett*, *supra*, upon which the appellant principally relies, is difficult to reconcile with the statutory construction which dispenses with the need of the offender's knowledge and wilfulness. The statute involved in the *Baender* case made penal the possession, without lawful authority, of any die in the likeness or similitude of a die designated for making genuine coin of the United States. There is no requirement in that statute that the condemned possession shall be with the possessor's knowledge and wilfulness. But the Supreme Court said that "The statute is not intended to include and make criminal a possession which is not conscious and willing." The basis for the construction thus placed upon the statute in the *Baender* case is not easy to differentiate. Counterfeiting is a direct and serious affront to the sovereign and usually perpetrated with effort at greatest secrecy, but the particular statutory provision<sup>4</sup> had originally contained the qualifying words "with intent to fraudulently and unlawfully use the same," which were eliminated when the subject matter of the original statute was incorporated in the Criminal Code,—a circumstance that might well have been taken to confirm that the deletion was designedly purposeful. None the less, on the authority of *United States v. Balint*, *supra*, we conclude that the construction of the statute before us presents no more than a

<sup>2</sup> See *Baender v. Barnett*, 255 U. S. 224.

<sup>3</sup> See grounds for exculpation specified in § 333 (c).

<sup>4</sup> § 169 of the Criminal Code, c. 127, Sec. 1, 26 Stat. 742.



question of legislative intent<sup>5</sup> and we perceive an intent in § 333 (a) to punish persons who introduced adulterated foods into interstate commerce regardless of their lack of knowledge or wilfulness.

In construing Section 2 of the Food and Drugs Act of 1906, 21 U. S. C. A. § 2, courts have held that guilty knowledge was not necessary to sustain a conviction.

See *Strong, Cobb & Co. v. United States* (C. C. A. 6, 1939) 103 F. 2d 671, and *United States v. Sprague* (D. C. E. D. N. Y., 1913) 208 F. 419. The analogy is obvious.

The second point raised by the appellant is without merit and does not require discussion.

[Conviction Affirmed]

The judgment will be affirmed.

## UNITED STATES v. DOTTERWEICH

United States Supreme Court. No. 5, October Term, 1943. Decided November 22, 1943. 320 U. S. 277. 64 S. Ct. 134. 88 L. ed. 48.  
Reversing 131 F. 2d 500. See page 262.

The provisions of Section 305 of the Act, requiring the Administrator, before reporting a violation for prosecution by a United States Attorney, to give the suspect an "opportunity to present his views," do not make the giving of such an opportunity a prerequisite to prosecution.

Section 305, Federal Food, Drug, and Cosmetic Act.

In a prosecution of a corporation and a corporate officer under the Act, the jury could find the officer guilty even though it failed to find the corporation guilty.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

If a guaranty under the Act immunizes shipments, it immunizes all involved in the shipment. But the fact that the guaranty would have been received by the corporation, had there been a guaranty, does not cut down the scope of responsibility of all who are concerned with transactions forbidden by Section 301.

Sections 301 (a), 301 (h), 303 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

The statute makes "any person" who violates Section 301 (a) guilty of a misdemeanor. It specifically defines "person" to include corporation. But the only way a corporation can act is through the individuals who act on its behalf.

Sections 201 (e), 301 (a), 301 (h), Federal Food, Drug, and Cosmetic Act.

<sup>5</sup> The legislative history of the statute throws some light on the nature of the penalties.

The report to the House of Representatives of Congressman Lea, Chairman of the House Committee on Interstate and Foreign Commerce, (Report No. 2139, to accompany S. 5, 75th Cong. 3rd Sess., p. 4), contains the statement, "[Section 333] . . . increases substantially the criminal penalties of the present law [the Food and Drugs Act of June 30, 1906, 34 Stat. 768, as amended, 21 U. S. C. A. §§ 1-15] which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business. Appropriate exemptions are provided for dealers who innocently receive and distribute illegal goods." During the debate upon

the bill Congressman Lea stated (Cong. Record, Vol. 83, Part 7, 75th Cong., 3rd Sess., 7775), "Then increased penalties are provided. Under the present law, as I recall, the maximum penalty is \$500 and the ordinary penalty is \$300. The bill we report fixes a maximum penalty of \$10,000 and a maximum time in jail of 3 years instead of 1 year as under the present law."

"The main object of so increasing these penalties is to provide suitable penalties due to the changed conditions since 1906. We have a great many institutions manufacturing drugs and foods that are very strong financially and we thought these higher penalties are justified in view of present conditions and to cover cases of the persistent violator."



Under Section 301, a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The District Court properly left the question of the responsibility of the corporate officer for the shipment to the jury, and there was sufficient evidence to support the jury's verdict.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The remedial purposes of the Act require that it be liberally construed.

Title, Federal Food, Drug, and Cosmetic Act.

Charles Fahy, Solicitor General; Wendell Berge, Assistant Attorney General; Oscar A. Provost and Edward G. Jennings, Special Assistants to Attorney General; Valentine Brooks, Attorney, for petitioner.

Robert J. Whissel, Buffalo, N. Y.; Samuel M. Fleischman, Buffalo, N. Y.; Francis E. Bagot, Buffalo, N. Y., for respondent.

[*Nature of Case*]

Mr. Justice FRANKFURTER delivered the opinion of the court: This was a prosecution begun by two informations, consolidated for trial, charging Buffalo Pharmacal Company, Inc. and Dotterweich, its president and general manager, with violations of the Act of Congress of June, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. §§ 301-392, known as the Federal Food, Drug, and Cosmetic Act. The Company, a jobber in drugs, purchased them from their manufacturers and shipped them, repacked under its own label, in interstate commerce. (No question is raised in this case regarding the implications that may properly arise when, although the manufacturer gives the jobber a guaranty, the latter through his own label makes representations.) The informations were based on § 301 of that Act (21 U. S. C. § 331), paragraph (a) of which prohibits "The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." "Any person" violating this provision is, by paragraph (a) of § 303 (21 U. S. C. § 333), made "guilty of a misdemeanor." Three counts went to the jury—two, for shipping misbranded drugs in interstate commerce, and a third, for so shipping an adulterated drug. The jury disagreed as to the corporation and found Dotterweich guilty on all three counts. We start with the finding of the Circuit Court of Appeals that the evidence was adequate to support the verdict of adulteration and misbranding. 131 F. 2d 500, 502.

[*Hearing Not Prerequisite to Prosecution;  
Manager Guilty Though Corporation Not*]

Two other questions which the Circuit Court of Appeals decided against Dotterweich call only for summary disposition to clear the path for the main question before us. He invoked § 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States attorney, to give the suspect an "opportunity to present his views." We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution. This Court so held in *United States v. Morgan*, 222 U. S. 274, in construing the Food and Drugs Act of 1906, 34 Stat. 768, and the legislative history to which the court below called attention abundantly proves that Congress, in the changed phraseology of 1938, did not intend to introduce a change of substance. 83 Cong. Rec. 7792-94. Equally baseless is the claim of Dotterweich that, having failed to find the corporation guilty, the jury could not find him guilty. Whether the jury's verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty instead of merely increasing, as it were, the cost of running the business of the corporation, is immaterial. Juries may indulge in precisely such motives or vagaries. *Dunn v. United States*, 284 U. S. 390.



*[Ground of CCA Decision]*

And so we are brought to our real problem. The Circuit Court of Appeals, one judge dissenting, reversed the conviction on the ground that only the corporation was the "person" subject to prosecution unless, perchance, Buffalo Pharmacal was a counterfeit corporation serving as a screen for Dotterweich. On that issue, after rehearing, it remanded the cause for a new trial. We then brought the case here, on the Government's petition for certiorari, 318 U. S. 753, because this construction raised questions of importance in the enforcement of the Federal Food, Drug, and Cosmetic Act.

The court below drew its conclusion not from the provisions defining the offenses on which this prosecution was based (§§ 301 (a) and 303 (a)), but from the terms of § 303 (c). That section affords immunity from prosecution if certain conditions are satisfied. The condition relevant to this case is a guaranty from the seller of the innocence of his product. So far as here relevant, the provision for an immunizing guaranty is as follows:

"No person shall be subject to the penalties of subsection (a) of this section . . . (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act . . ."

The Circuit Court of Appeals found it "difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one." 131 F. 2d 500, 503. And so it cut down the scope of the penalizing provisions of the Act to the restrictive view, as a matter of language and policy, it took of the relieving effect of a guaranty.

*[Law Dispenses with Awareness of Wrongdoing as Element of Crime]*

The guaranty clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation

thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128. The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are "punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares . . ." *United States v. Johnson*, 221 U. S. 488, 497-98.

*[Liability of Corporations and Individuals]*

The statute makes "any person" who violates § 301 (a) guilty of a "misdemeanor." It specifically defines "person" to include "corporation." § 201 (e). But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central & H. R. R. Co. v. United States*, 212 U. S. 481. And the historic conception of a "misdemeanor" makes all those responsible for it equally guilty, *United States v. Mills*, 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U. S. C. § 550). If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the "person" who violates § 301 (a) is a corporation, although from the point of view of action the individuals are the corporation. As a matter of legal development, it has taken time to establish criminal liability also for a corporation and not merely for its agents. See *New York Central & H. R. Co. v. United States*, *supra*. The history of federal food and drug legislation is a good illustration of the elaborate phrasing that was in earlier days deemed necessary to fasten criminal liability on corporations.



Section 12 of the Food and Drugs Act of 1906 provided that, "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." By 1938, legal understanding and practice had rendered such statement of the obvious superfluous. Deletion of words—in the interest of brevity and good draftsmanship<sup>1</sup>—superfluous for holding a corporation criminally liable can hardly be found ground for relieving from such liability the individual agents of the corporation. To hold that the Act of 1938 freed all individuals, except when proprietors, from the culpability under which the earlier legislation had placed them is to defeat the very object of the new Act. Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906." (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws," but on the contrary "it must strengthen and extend that law's protection of the consumer." (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.) If the 1938 Act were construed as it was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a "license fee for the conduct of an illegitimate business."<sup>2</sup> A corporate officer, who even with "intent to defraud or mislead" (§ 303 b), introduced adulterated or misbranded drugs into interstate commerce could not be held culpable for conduct which was indubitably outlawed by the 1906 Act. See, e. g., *United States v. Mayfield*, 177

F. 765. This argument proves too much. It is not credible that Congress should by implication have exonerated what is probably a preponderant number of persons involved in acts of disobedience—for the number of non-corporate proprietors is relatively small. Congress, of course, could reverse the process and hold only the corporation and allow its agents to escape. In very exceptional circumstances it may have required this result. See *Sherman v. United States*, 282 U. S. 25. But the history of the present Act, its purposes, its terms, and extended practical construction lead away from such a result once "we free our minds from the notion that criminal statutes must be construed by some artificial and conventional rule." *United States v. Union Supply Co.*, 215 U. S. 50, 55.

[*Want of Guaranty Does Not Cut Scope of Responsibility*]

The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there had been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301. To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor. To read the guaranty section, as did the court below, so as to restrict liability for penalties to the only person who normally would receive a guaranty—the proprietor—disregards the admonition that "the meaning of a sentence is to be felt rather than to be proved." *United States v. Johnson*, 221 U. S. 488, 496. It also reads an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act.

<sup>1</sup> "The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions." S. Rep. No. 152, 75th Cong., 1st Sess., p. 2.

<sup>2</sup> In describing the penalty provisions of § 303, the House Committee reported that the Bill

"increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business." H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4.



*[Responsibility of Accused Depends  
on Evidence]*

The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement of § 301 (a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on "conscience and circumspection in prosecuting officers," *Nash v. United States*, 229 U. S. 373, 378, even when the consequences are far more

drastic than they are under the provision of law before us. See *United States v. Balint, supra* (involving a maximum sentence of five years). For present purpose it suffices to say that in what the defense characterized as "a very fair charge" the District Court properly left the question of the responsibility of Dotterweich for the shipment to the jury, and there was sufficient evidence to support its verdict.

*Judgment reversed.*

### Dissenting Opinion

MR. JUSTICE MURPHY: Our prime concern in this case is whether the criminal sanctions of the Federal Food, Drug, and Cosmetic Act of 1938 plainly and unmistakably apply to the respondent in his capacity as a corporate officer. He is charged with violating § 301 (a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation.

It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But in the absence of clear statutory authorization it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous. Accordingly that which Chief Justice Marshall has called "the tenderness of the law for the rights of individuals"<sup>1</sup> entitles each person, regardless of economic or social status, to an unequivocal warning from the legislature as to whether he is within the class of persons subject to vicarious liability. Congress cannot be

<sup>1</sup> *United States v. Wiltberger*, 5 Wheat. 76, 95



deemed to have intended to punish anyone who is not "plainly and unmistakably" within the confines of the statute. *United States v. Lacher*, 134 U. S. 624, 628; *United States v. Gradwell*, 243 U. S. 476, 485.

Moreover, the fact that individual liability of corporate officers may be consistent with the policy and purpose of a public health and welfare measure does not authorize this Court to impose such liability where Congress has not clearly intended or actually done so. Congress alone has the power to define a crime and to specify the offenders. *United States v. Wiltberger*, 5 Wheat. 76, 95. It is not our function to supply any deficiencies in these respects, no matter how grave the consequences. Statutory policy and purpose are not constitutional substitutes for the requirement that the legislature specify with reasonable certainty those individuals it desires to place under the interdict of the Act. *United States v. Harris*, 177 U. S. 305; *Sarlls v. United States*, 152 U. S. 570.

Looking at the language actually used in this statute, we find a complete absence of any reference to corporate officers. There is merely a provision in § 303 (a) to the effect that "any person" inadvertently violating § 301 (a) shall be guilty of a misdemeanor. Section 201 (e) further defines "person" as including an "individual, partnership, corporation, and association."<sup>2</sup> The fact that a

corporate officer is both a "person" and an "individual" is not indicative of an intent to place vicarious liability on the officer. Such words must be read in light of their statutory environment.<sup>3</sup> Only if Congress has otherwise specified an intent to place corporate officers within the ambit of the Act can they be said to be embraced within the meaning of the words "person" or "individual" as here used.

Nor does the clear imposition of liability on corporations reveal the necessary intent to place criminal sanctions on their officers. A corporation is not the necessary and inevitable equivalent of its officers for all purposes.<sup>4</sup> In many respects it is desirable to distinguish the latter from the corporate entity and to impose liability only on the corporation. In this respect it is significant that this Court has never held the imposition of liability on a corporation sufficient, without more, to extend liability to its officers who have no consciousness of wrongdoing.<sup>5</sup> Indeed, in a closely analogous situation, we have held that the vicarious personal liability of receivers in actual charge and control of a corporation could not be predicated on the statutory liability of a "company," even when the policy and purpose of the enactment were consistent with personal liability. *United States v. Harris, supra*.<sup>6</sup> It follows that express statutory pro-

<sup>2</sup> The normal and necessary meaning of such a definition of "person" is to distinguish between individual enterprises and those enterprises that are incorporated or operated as a partnership or association, in order to subject them to the Act. This phrase cannot be considered as an attempt to distinguish between individual officers of a corporation and the corporate entity. Lee, "Corporate Criminal Liability," 28 Col. L. Rev. 1, 181, 190.

<sup>3</sup> Compare *United States v. Cooper Corp.*, 312 U. S. 600, 606, and *Davis v. Pringle*, 268 U. S. 315, 318, holding that the context and legislative history of the particular statutes there involved indicated that the words "any person" did not include the United States. But in *Georgia v. Evans*, 316 U. S. 159, and *Ohio v. Helvering*, 292 U. S. 360, these considerations led to the conclusion that "any person" did include a state. See also 40 Stat. 1143, which specifically includes officers within the meaning of "any person" as used in the Revenue Act of 1918.

<sup>4</sup> In *Park Bank v. Remsen*, 158 U. S. 337, 344, this Court said, "It is the corporation which is given the powers and privileges and made subject to the liabilities. Does this carry with it an imposition of liability upon the trustee or other officer of the corporation? The officer is not the corporation; his liability is personal, and not that of the corporation, nor can it be counted among the powers and privileges of the corporation."

<sup>5</sup> For an analysis of the confusion on this matter in the state and lower federal courts, see Lee, "Corporate Criminal Liability," 28 Col. L. Rev. 1, 181.

<sup>6</sup> In that case we had before us Rev. Stat. §§ 4386-4389, which penalized "any company, owner or custodian of such animals" who failed to comply with the statutory requirements as to livestock transportation. A railroad company violated the statute and the government sought to impose liability on the receivers who were in actual charge of the company. It was argued that the word "company" embraced the natural persons acting on behalf of the company and that to hold such officers and receivers liable was within the policy and purpose of so humane a statute. We rejected this contention in language peculiarly appropriate to this case (177 U. S. at 309):

"It must be admitted that, in order to hold the receivers, they must be regarded as included in the word 'company'. Only by a strained and artificial construction, based chiefly upon a consideration of the mischief which the legislature sought to remedy, can receivers be brought within the terms of the law. But can such a kind of construction be resorted to in enforcing a penal statute? Giving all proper force to the contention of counsel of the government, that there has been some relaxation on the part of the courts in applying the rule of strict construction to such statutes, it still remains that the intention of a penal statute must be found

(Footnote 6 is continued on page 284.)



visions are necessary to satisfy the requirement that officers as individuals be given clear and unmistakable warning as to their vicarious personal liability. This Act gives no such warning.

This fatal hiatus in the Act is further emphasized by the ability of Congress, demonstrated on many occasions, to apply statutes in no uncertain terms to corporate officers as distinct from corporations.<sup>7</sup> The failure to mention officers specifically is thus some indication of a desire to exempt them from liability. In fact the history of federal food and drug legislation is itself illustrative of this capacity for specification and lends strong support to the conclusion that Congress did not intend to impose liability on corporate officers in this particular Act.

Section 2 of the Federal Food and Drugs Act of 1906, as introduced and passed in the Senate, contained a provision to the effect that any violation of the Act by a corporation should be deemed to be the act of the officer responsible therefore and that such officer might be punished as though it were his personal act.<sup>8</sup> This clear imposition of criminal responsibility on corporate officers, however, was not carried over into the statute as finally enacted. In its place appeared merely the provision that "when

in the language actually used, interpreted according to its fair and obvious meaning. It is not permitted to courts, in this class of cases, to attribute inadvertence or oversight to the legislature when enumerating the classes of persons who are subjected to a penal enactment, nor to depart from the settled meaning of words or phrases in order to bring persons not named or distinctly described within the supposed purpose of the statute."

<sup>7</sup> "Whenever a corporation shall violate any of the penal provisions of the antitrust laws, such violation shall be deemed to be also that of the individual directors, officers, or agents of such corporation who shall have authorized, ordered, or done any of the acts constituting in whole or in part such violation." 15 U. S. C. § 24.

"The courts of bankruptcy . . . are invested with such jurisdiction at law and in equity as will enable them to . . . (4) arraign, try, and punish bankrupts, officers, and other persons, and the agents, officers, members of the board of directors or trustees, or other similar controlling bodies, of corporations for violations of the provisions contained in this title." 11 U. S. C. § 11.

"Any such common carrier, or any officer or agent thereof, requiring or permitting any employee to go, be, or remain on duty in violation of the next preceding section of this chapter shall be liable to a penalty . . ." 45 U. S. C. § 63.

"A mortgagor who, with intent to defraud,

construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation . . . within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation . . . as well as that of the person."<sup>9</sup> This provision had the effect only of making corporations responsible for the illegal acts of their officers and proved unnecessary in view of the clarity of the law to that effect. *New York Central & H. R. R. Co. v. United States*, 212 U. S. 481.

The framers of the 1938 Act were aware that the 1906 Act was deficient in that it failed "to place responsibility properly upon corporate officers."<sup>10</sup> In order "to provide the additional scope necessary to prevent the use of the corporate form as a shield to individual wrongdoers,"<sup>11</sup> these framers inserted a clear provision that "whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such viola-

violates any provision of subsection F, section 924, and if the mortgagor is a corporation or association, the president or other principal executive officer of the corporation or association, shall upon conviction thereof be held guilty of a misdemeanor . . ." 46 U. S. C. § 941 (b).

<sup>8</sup> S. 88, 59th Cong., 1st Sess. Senator Heyburn, one of the sponsors of S. 88, stated that this was "a new feature in bills of this kind. It was intended to obviate the possibility of escape by officers of a corporation under a plea, which has been more than once made, that they did not know that this was being done on the credit of or on the responsibility of the corporation." 40 Cong. Rec. 894.

<sup>9</sup> 34 Stat. 772, 21 U. S. C. § 4.

<sup>10</sup> Senate Report No. 493, 73d Cong., 2d Sess., p. 21.

<sup>11</sup> *Ibid.*, p. 22. This report also stated that "it is not, however, the purpose of this paragraph to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law. However, if a director or officer personally orders his subordinate to do an act in violation of the law, there is no reason why he should be shielded from personal responsibility merely because the act was done by another and on behalf of a corporation."



tion."<sup>12</sup> This paragraph, however, was deleted from the final version of the Act.

We cannot presume that this omission was inadvertent on the part of Congress. *United States v. Harris, supra* at 309. Even if it were, courts have no power to remedy so serious a defect, no matter how probable it otherwise may appear that Congress intended to include officers; "probability is not a guide which a court, in construing a penal statute, can safely take." *United States v. Wiltberger, supra* at 105. But the framers of the 1938 Act had an intelligent comprehension of the inadequacies of the 1906 Act and of the unsettled state of the law. They recognized the necessity of inserting clear and unmistakable language in order to impose liability on corporate officers. It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability. Thus to apply the sanctions of this Act to the respondent would be contrary to the intent of Congress as expressed in the statutory language and in the legislative history.

The dangers inherent in any attempt to

create liability without express Congressional intention or authorization are illustrated by this case. Without any legislative guides, we are confronted with the problem of determining precisely which officers, employees and agents of a corporation are to be subject to this Act by our fiat. To erect standards of responsibility is a difficult legislative task and the opinion of this Court admits that it is "too treacherous" and a "mischievous futility" for us to engage in such pursuits. But the only alternative is a blind resort to "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries." Yet that situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law. I therefore cannot approve the decision of the Court in this case.

Mr. Justice ROBERTS, Mr. Justice REED and Mr. Justice RUTLEDGE join in this dissent.

**A. O. BARNES AND O. C. RAPIER, JR., CO-PARTNERS,  
TRADING AS S. O. BARNES & SON,  
v. UNITED STATES**

United States Circuit Court of Appeals for the Ninth Circuit. No. 10,315.  
May 8, 1944. 142 F. 2d 648.

Liability under the Act may be avoided if persons introducing into interstate commerce adulterated or misbranded food have obtained a guaranty from the person from whom they in good faith received the product.

Section 303 (c), Federal Food, Drug, and Cosmetic Act.

Under such circumstances, the liability is then imposed on the guarantor. This imposition of liability is obtained through Section 301 (h).

Section 301 (h), Federal Food, Drug, and Cosmetic Act.

In a prosecution for having given a false guaranty with respect to vitamin tablets, it was held that the prohibition against the giving of a false guaranty clearly includes an agreement between parties who intend that it shall cover each of a series of transactions.

Sections 301 (h), 303 (c), 402 (b), 403 (a), Federal Food, Drug, and Cosmetic Act

<sup>12</sup> This provision appears in several of the early versions of the Act introduced in Congress. S. 1944, 73d Cong., 1st Sess., § 18 (b); S. 2000, 73d Cong., 2d Sess., § 18 (b); S. 2800, 73d Cong., 2d Sess., § 18 (b); S. 5, 74th Cong., 1st Sess., § 709 (b); S. 5, 74th Cong., 2d Sess., § 707 (b), as reported to the House, which substituted the word "personally" for the word "authorized" in the last clause of the paragraph

quoted above. A variation of this provision appeared in S. 5, 75th Cong., 1st Sess., § 2 (f), and made a marked distinction between the use of the word "person" and the words "director, officer, employee, or agent acting for or employed by any person." All of these bills also contained the present definition of "person" as including "individual, partnership, corporation, and association."



In a prosecution for having given a false guaranty, it was held that under the facts there was only one guaranty, and its falsity, though by definition amounting to adulteration and misbranding, in truth arose out of the same deficiency of vitamin potency in the vitamin tablets involved.

Sections 301 (h), 303 (a), Federal Food, Drug, and Cosmetic Act.

It is permissible to allege the commission of an offense in several separate counts. But if proof of guilt under each count rests upon the same facts, it is error to impose separate penalties for each count.

Sections 301 (a), 301 (h), 303 (a), Federal Food, Drug, and Cosmetic Act.

"Commerce," as used in the Act, is not confined in meaning to the actual transportation of articles across state lines, but includes the whole transaction of which such transporting is a part. It cannot be qualified or avoided by the technicalities of the law of sales regarding passing of title.

Section 201 (b), Federal Food, Drug, and Cosmetic Act.

Assuming that the defendants were but agents or bailees of the vendee at the time of the delivery of the product involved to the carrier, they nonetheless were within the purview of the Act.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

Liability cannot be avoided by one who manufactures or processes food because of the fact that the product conforms to an order and the labels describing the product are supplied by the vendee.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act is the protection of the consuming public. Those who ship in interstate commerce products coming within the scope of its protection must do so at their peril if the standards of the Act are not observed.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

John D. Hoyt, Los Angeles, Cal., for appellant.

Charles H. Carr, U. S. Attorney, James M. Carter, Betty Marshall Graydon, Assistant U. S. Attorneys, Los Angeles, Cal., for appellee.

Before: WILBUR, DENMAN and STEPHENS, Circuit Judges.

#### *[Appeal From Conviction]*

DENMAN, Circuit Judge: This is an appeal from a judgment of the district court finding Alfred O. Barnes and Oliver C. Rapier, Jr. guilty on all four counts of an information charging them with violating the Federal Food, Drug, and Cosmetic Act.

#### *[Proceedings Below]*

The defendants entered a plea of not guilty. The case was tried by the court, defendants having waived a jury. A decree was entered finding them guilty as charged and fines of \$50.00 were imposed on each defendant for violation of each count.

#### *[Description of Defendants]*

The defendants, Barnes and Rapier, are co-partners trading as S. O. Barnes & Son, and are engaged in the manufacture of pharmaceutical products on specification for dealers in those products. Their plant is in Gardena, California.

#### *[Charges of Information]*

The first two counts of the information charged them with having given a false guaranty in violation of 21 U. S. C. § 331 (h). The first count was predicated on falsity arising out of shipping adulterated food under a guaranty. The second count was predicated on falsity arising out of misbranding. Under the statute, adulteration of food is in part defined as the omission in whole or in part of any valuable constituent of a product. 21 U. S. C. § 342 (b)(1). Misbranding is in part defined as false labeling in any particular. 21 U. S. C. § 343 (a).

#### *[Guaranty Alleged and Found]*

In support of these charges it was alleged and found that a guaranty of the nature described in 21 U. S. C. § 333 (c) (2) was executed by S. O. Barnes & Son in favor of McCollum Laboratories, Inc., of Hollywood, California, on January 2, 1941, providing that "\* \* \* no food \* \* \* constituting or



being part of any shipment or other delivery now or hereafter made \* \* \* will \* \* \* be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act." It was further guaranteed "\* \* \* that the vitamin potency of the Vitamin A & D Tablets as furnished by us to the McCollum Laboratories, shall not be below the potency" of "\* \* \* 3000 I. U. Vitamin A per tablet" and "\* \* \* 300 I. U. Vitamin D per tablet." It was also provided that the guaranty should be continuing and binding until revoked.

*[Effect of Guaranty]*

Under the present Act persons are subject to its penalties for introducing or delivering for introduction into interstate commerce any food that is adulterated or misbranded. 21 U. S. C. § 331 (a). But liability may be avoided if such persons have obtained a guaranty of the person from whom they in good faith received the product. 21 U. S. C. § 333 (c) (2). Under such circumstances, the liability is then imposed upon the guarantor. This imposition of liability is obtained through 21 U. S. C. § 331 (h) which creates a penalty for the giving of a false guaranty. Thus under the statutory scheme the falsity described in the latter section must be defined in terms of the conduct prohibited by § 331 (a).

*[Vitamin Tablets Deficient]*

During July of 1941 certain deliveries of vitamin tablets were made for McCollum Laboratories by defendants for delivery into interstate commerce from Gardena, California, to Portland Oregon. The labels on the bottles containing the tablets represented their vitamin content to be 3000 I. U. of A. and 300 I. U. of D. It was found that the tablets were deficient in both vitamins.

*[Appellants' Contention]*

Appellants' chief contention regarding the first two counts is that they fail to charge a crime under 21 U. S. C. § 331 (h), for there is no allegation that the guaranty was false at the time of its execution and that the shipments in July of tablets not conforming to the terms of the guaranty given seven months previously cannot make false that which was made in good faith at the time of its execution.

*[Error to Levy Separate Fines for One Offense]*

We cannot agree that these counts fail to charge a violation of the statute. By the

terms of the guaranty alleged and proved, it was intended to cover all deliveries of vitamin tablets to McCollum Laboratories until revoked. It was alleged and proved that no revocation had been made prior to the deliveries of the deficient tablets. Regardless of the administrative regulations relied upon by the appellee giving the exemption of 21 U. S. C. § 333 (c) (2) to the holder of a continuing guaranty, 21 C. F. R. § 1.19, we believe a fair interpretation of the statute prohibiting the giving of false guaranties clearly includes an agreement between parties who intend that it shall cover each of a series of transactions. But we agree with appellants' further contention that counts one and two merely charge one offense. Under the facts there was only one guaranty and its falsity, though by definition amounting to adulteration and misbranding, in truth arose out of the same deficiency of vitamin potency in the tablets. It is permissible to allege the commission of an offense in several separate counts. *United States v. Schider*, 246 U. S. 519, but if proof of guilt under each count rests upon the same facts it is error to impose separate sentences or fines for each count. *Chrysler v. Zerbst*, 81 F. (2d) 975 (CCA-10). Thus the trial court erred in levying separate fines upon defendants for the violation of both count one and count two of the information.

*[Disparity Between Quantity of B-2 Represented and Present]*

The third and fourth counts of the information charged defendants with introducing into interstate commerce a consignment of adulterated and misbranded tablets from Gardena, California, to Dr. John X. Loughran of Long Island, New York. These tablets were contained in bottles labeled Vitamin B Complex followed by representations of quantities of the various constituent elements of that vitamin complex, including 60 Gammas of B-2 (Riboflavin). It was alleged and proved that these tablets contained not more than 40 Gammas of B-2. Such a disparity between the quantity represented and the amount actually present in the tablets is obviously within the prohibition of the Act.

*[Statement as to Vitamin B Complex Misleading]*

The fourth count alleged further that the statement "Vitamin B Complex" on the label was misleading to the consuming pub-



lic for it suggested and implied that the tablets contained consequential amounts of all the elements of the complex when, in fact, these tablets had inconsequential amount of B-2 and nicotinic acid.

[*Appellants' Defense*]

Appellants do not contest the drawn inference of misbranding arising out of the use of the term Vitamin B Complex, but assert that the third and fourth counts fail to charge an offense because it is clear from the label that it was designed by Dr. Loughran and therefore they cannot be liable for any direct or implied representations arising from its use. It was further asserted in their defense that they were but little better than bailees at the time of the shipment.

[*Liability Not Avoided Though Label Complies with Order*]

The broad language of the statute does not permit such defenses. It is directed to any person who introduces or delivers for introduction into interstate commerce any food that is adulterated or misbranded. Commerce so used in the statute is not confined in meaning to the actual transportation of articles across state lines, but includes the whole transaction of which such transporting is a part, *Santa Cruz Co. v. Labor Board*, 303 U. S. 453, 463; *Dahnke-Walker Co. v. Bondurant*, 257 U. S. 282, 291, and it cannot be qualified or avoided by the technicalities of the law of sales regarding passing of title. *Dozier v. Alabama*, 218 U. S. 124, 128. Thus even assuming appellants were but agents or bailees of the vendee at the time of delivery of the product to the carrier for shipment to New York, they nonetheless were within the purview of the Act. *Lynch v. Magnavox Co.*, 94 F. (2d) 883, 890 (CCA-9). Nor can liability be avoided by one who manufactures or processes foods by the fact that the product conforms to an order and the labels describing the product are supplied by the vendee.

The purpose of the Act is the protection of the consuming public. *McDermott v. Wisconsin*, 228 U. S. 115, 130. Those who ship in interstate commerce products coming within the scope of its protection must do so at their peril if the standards of the Act are not observed. *United States v. Dotterweich* (November 22, 1943) 320 U. S. 277.

[*Judgment Reversed in Part and Affirmed in Part*]

The judgment is reversed as to the conviction on the second count. Otherwise it is affirmed.

**Concurring and Dissenting Opinion**

STEPHENS, Circuit Judge, concurring and dissenting: I concur in the affirmance of the judgment pronounced by virtue of conviction under counts one, three and four of the indictment. I dissent as to the reversal of the judgment pronounced by virtue of conviction under count two of the indictment. I think the indictment states separate offenses as to counts one and two.

If I am wrong in this, and I think I am not, then I am at a loss to know by what authority this court elects to affirm the judgment under count one rather than under count two. Here are two separate convictions under separate counts for which the court pronounced two separate penalties. The majority state that the counts are based upon different acts. I quote from the opinion. "The first count was predicated on falsity arising out of shipping adulterated food under a guaranty. The second count was predicated on falsity arising out of misbranding." The fact that the court thought the defendants should be punished as severely for one as for the other infraction does not solve the difficulty. If the trial court had given twice the penalty under count one that it did under count two, by what token would the court decide to affirm as to one and reverse as to the other?



UNITED STATES v. LORD-MOTT CO., INC.

United States District Court for the District of Maryland. No. 20250, Criminal.  
July 18, 1944. 57 F. Supp. 128.

A court, sitting as a jury in a criminal case, must instruct itself in the same manner that it must instruct a jury with respect to the constitutional rights and privileges of the defendant and the requirement as to burden of proof.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

The case involved prosecution of the defendant for having introduced into interstate commerce canned peas which did not conform to the standard of quality therefor promulgated under the Act. The defense of invalidity of the regulation may be raised in a criminal case in advance of the trial.

Sections 301 (a), 301 (b), 303 (a), 401, 403 (g), 403 (h), Federal Food, Drug, and Cosmetic Act. . .

Where the question of validity of a regulation is a factual one, the weight of the credible evidence controls.

Section 401, Federal Food, Drug, and Cosmetic Act.

Independently of Section 701 (f) (6), in a criminal proceeding of the kind involved, in the absence of some clearly expressed valid provision in the law itself for an exclusive method of testing the validity of regulations or orders of the Administrator, a defendant is not precluded from raising the question at the trial.

Sections 401, 403 (g), 403 (h), 701 (a), 701 (f), Federal Food, Drug, and Cosmetic Act.

A regulation fixing a maximum alcohol insoluble solids content of canned peas imposed an undue hardship upon canners in the Tri-State Area (Maryland, Delaware, and New Jersey) and was invalid.

Sections 401, 701 (a), 701 (f), Federal Food, Drug, and Cosmetic Act.

In promulgating a regulation fixing the maximum insoluble solids content of canned peas, the Administrator over-emphasized the factor of consumer taste and acted in undue derogation of the rights of growers and canners.

Sections 401, 701 (a), Federal Food, Drug, and Cosmetic Act.

The defendant was not controlled by what was proved or decided by the administrative hearing which had led to the promulgation of the regulation, but had a right to have the trial court decide the question of the regulation's validity upon the evidence produced before it.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The Administrator does not have unlimited power with respect to promulgating food regulations. He has only such power as is expressly given him or as may be reasonably implied from the terms of the Act, so that the intent of the Act may be effectively carried out.

Section 401, Federal Food, Drug, and Cosmetic Act.

C. Ross McKenrick, Assistant U. S. Attorney; Joseph L. Maguire, Senior Attorney, Federal Security Agency, for the U. S.

Eli Frank, John Henry Skeen, for defendant.



## Opinion

*[Court's Findings of Not Guilty]*

COLEMAN, District Judge: The defendant here, a Maryland canning corporation, is charged, by information, with having violated a Government regulation for determining, in part, the standard of quality for canned peas.

The Court, sitting as a jury, a jury having been waived, finds the defendant not guilty. It finds that the Regulation upon alleged violations of which the Information is based, is invalid because it exceeds the authority granted to the Federal Security Administrator, commonly known as the Administrator, by the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (21 U. S. C. A. Secs. 301-392 incl.), to pass such a regulation, and therefore the Court's verdict must be not guilty as to the defendant.

*[Question of Validity Controlled by Weight of Credible Evidence]*

It is, of course, true that this Court, sitting as a jury in a criminal case, must instruct itself in the same manner that it must instruct a jury with respect to the Constitutional rights and privileges of the defendant, and the requirement as to burden of proof, which is that the Government shall sustain the burden of proof to the satisfaction of the jury (or the court sitting as a jury) beyond a reasonable doubt, upon the evidence, and only upon the evidence, as adduced at the trial. However, in the present case there is raised a defense that may be raised in any criminal case in advance of the actual trial by motion, or demurrer, or, as in the present case, by oral motion supported by testimony taken at the trial, *i. e.*, the defense of invalidity of the Regulation itself. In such case, where the question of validity is a factual one, the weight of the credible evidence controls. The proof of validity—or invalidity—is not required to be established—as is the guilt of the accused once the Regulation is found to be valid—beyond a reasonable doubt. One may be guilty of violating a law or regulation but if the law or regulation is found to be unconstitutional or invalid for any reason, then, of course, it becomes unnecessary to determine whether or not the Government has sustained the burden of proof of guilt to the satisfaction of the jury, or the Court sitting as a jury, beyond a reasonable doubt. So, to summarize, as the Court sees the weight of the credible evidence, it requires the Court to hold that by prom-

ulgating the Regulation in controversy the Administrator exceeded the limits of his authority as respects the subject matter upon which it was exercised.

*[Provisions of Food, Drug, & Cosmetic Act]*

The pertinent sections of the Federal Food, Drug, and Cosmetic Act, are the following: First, among the enumerated acts and the causing thereof which are prohibited are

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded,"

and

"(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce." (21 U. S. C. A. Sec. 331, subsections (a) and (b)).

Second, it is provided that any person who violates the foregoing provisions

"shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine." (21 U. S. C. A. Sec. 333, subsec. (a)).

Third, the law provides that

"Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate the regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container." (21 U. S. C. A., Sec. 341.)

Fourth, the law provides that

"A food shall be deemed to be misbranded—

\* \* \* \* \*

"(h) if it purports to be or is represented as—

"(1) a food for which a standard of quality has been prescribed by regulations as provided by Section 341, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;" (21 U. S. C. A. Sec. 343, subsec. (h)).



Fifth,

"(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is hereby vested in the Administrator."

(21 U. S. C. A. Sec. 371, subsec. (a)).

Following this subsection are detailed provisions covering the conduct of hearings; the effectiveness of definitions and standards of identity; the promulgation of regulations and proposed changes in regulations; the making of orders and the review of orders promulgated as a result of hearings, including provisions for review by the Circuit Court of Appeals for the Circuit wherein any person who would be adversely affected by a given order resides, or has his principal place of business; with provision also for final review by the Supreme Court. Finally, there is the following:

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

(21 U. S. C. A. Sec. 371 (f) (6)).

*[Defendant in Criminal Prosecution May  
Question Validity of Regulation]*

We reach the conclusion that, independently of the provision just quoted, in a criminal proceeding of this kind in the absence of some clearly expressed, valid provision in the law itself for an exclusive method of testing the validity of regulations or orders of the Administrator, a defendant is not precluded from raising the question at the trial, as has been done in the present case.

*[Administrator Exceeded Authority as to  
Alcohol Insoluble Solids]*

Having thus found that the defendant had a right to be heard, *ab initio*, in this proceeding with respect to the validity of the regulation, regardless of what the testimony, taken at a hearing conducted, as provided by the Act, on behalf of the Administrator, may show; regardless of the motives of the Administrator in promulgating the regulation, and regardless of whether or not the defendant was present at such hearing or was opposed to or in favor of the Regulation, we pass to a recital of the reasons why we think the Administrator exceeded his authority in the present instance, and why, therefore, the defendant was not compelled to meet the requirements of the Regulation with respect to the one specific

part of it which is here involved, namely, the so-called alcohol insoluble solids, or the "AIS", method of testing quality.

*[Tolerance Allowed by Administrator in AIS  
Method Is Unjust and Unreasonable]*

We find from the weight of the credible evidence in the present case that, while this "AIS" regulation embodies a fair and reasonable way *per se* of determining the grade of canned peas, which, in fact, the defendant admits, nevertheless the Administrator, in the tolerance allowed in the requirements imposed by that method, has failed to make the application of that method just and reasonable to the present defendant and all others in like circumstances.

*[Findings of Fact Adopted by Secretary  
of Agriculture]*

Among the suggested findings of fact as reported in the Federal Register of Saturday, November 25, 1939, pages 4679-4682, are the following which were ultimately adopted by the Secretary of Agriculture as the Department findings and formed the basis for the Regulation here in question, and which appear in the Federal Register for Saturday, February 24, 1940, pages 741-744:

"48. The extent to which insoluble solids are present governs the mealiness of peas when they are chewed. The art of canning was first devised for the purpose of preserving the succulence of fresh vegetables, and canned peas are a product which simulates, in so far as possible, peas taken direct from the garden, cooked and eaten. Such peas are not excessively mealy, and the quality of canned peas is lowered, depending in a large measure on the extent to which they are mealy."

"49. Mealiness in peas becomes excessive when their content of insoluble solids is such that the peas do not have the proper degree of succulence when eaten. Such mealiness can be measured objectively."

"50. Mealiness and insoluble solids content are definitely and directly correlated, and the determination of the insoluble solids gives an accurate index to the mealiness of canned peas."

"51. Canned peas are excessively mealy in the consensus of consumer taste, in the case of early June peas, when they contain more than 23.5 per cent of solids insoluble in alcohol; and in the case of sweet peas, when they contain more than 21 per cent of solids insoluble in alcohol."



*[Standard of Quality for Canned Peas  
Promulgated]*

Then there follow numerous references to the testimony taken at the hearing duly called and held by the Secretary of Agriculture, for the purpose, among other things, of fixing and establishing a reasonable standard of quality for canned peas, supporting the suggested findings. Also, under "Suggested Conclusion in the Form of a Regulation," p. 4682, we find the matter summarized as follows:

Section 51.001, "Canned Peas—Quality: label statement of substandard quality. (a) The standard of quality for canned peas is as follows:

"(6) The alcohol insoluble solids of Alaska or other smooth skin varieties of peas from the container are not more than 23.5 per cent, and of sweet, wrinkled varieties, not more than 21 per cent."

Then there follows a detailed description of how the peas shall be tested to determine whether or not they meet the above quoted requirement, as well as the other requirements set forth in the same regulation respecting weight, etc. Since, as already stated, defendant admits the reasonableness of the method prescribed in the Regulation for determining the alcohol-insoluble solids content, it is unnecessary to discuss or to describe that method.

What has just been quoted was embodied, *verbatim*, as Regulation No. 51.001, promulgated on the 23rd of February, 1940, and appearing in the Federal Register for Saturday, February 24, 1940, p. 744.

*[Testimony of Witnesses for Defendant Given  
Greater Weight Than Testimony of  
Witnesses for Government]*

As has just been said, the Court is satisfied from the weight of the credible evidence introduced in the present case that this figure of 23.5 per cent imposed an undue hardship upon canners in this area, known as the Tri-State Area, comprising Maryland, Delaware and New Jersey, such as the defendant. The testimony is not all to that effect, and due credence must be given to the opposing testimony of the witnesses for the Government. But the Court can not blink the fact that they are naturally interested or biased, in seeing that their work or the work of their associates in this matter is upheld, and when such highly qualified witnesses as the head of the Horticultural Department of the University of Maryland and the Executive Secretary of the Tri-State Packers Association testify, as they did, that it is their definite view

that the allowable tolerance for all varieties of Alaska peas works an undue hardship in that it does not give sufficient tolerance to enable such peas grown in this area to be marketed with reasonable readiness and profit, the Court feels that their testimony must be given greater weight than the testimony of the Government's witnesses.

*[Decline of Pea-Packing in Tri-State Area  
Due to Rigid AIS Requirement]*

It is uncontradicted by the testimony in the present case that a large proportion of packs in recent years in this general area are recognized as not meeting the standard required, by this test, that is, they are labeled sub-standard. For example, in 1941, 28 per cent of the pack was sub-standard. Also, it is uncontradicted that in this area, pea-packing has been declining out of proportion to the decline throughout other sections of the country. It is asserted on behalf of defendant, and the Court feels it has not been successfully contradicted, that this rigid "AIS" requirement has had a material influence in producing these conditions.

*[Opinions of Witnesses as to Increased  
Tolerance]*

One or more of the witnesses testifying for the defendant have stated what they thought would be a proper, somewhat increased tolerance under the "AIS" requirement. One witness has stated that in his opinion it ought to be placed at 24.5 in place of 23.5. Other witnesses stated that they were not entirely sure in their own minds as to just what the figure should be, but that if the law does not allow the setting of a standard for each different grade of every variety of pea, then the blanket tolerance should be somewhere in excess of 23.5.

*[Regulation Fails Because It Imposes  
Unwarranted Hardship]*

Taking all of the foregoing into consideration,—and the Court does not mean that because it has specifically referred to certain parts of the testimony, such is all of the testimony that supports its conclusion,—but taking the testimony as a whole, as the Court sees it, we have here a clear case where an administrative agency has promulgated a regulation, the force and effect of which is to impose a hardship upon those affected by it which is not warranted or required by either the expressed or implied language of the statute, and that, therefore, such a regulation must fail. However, we do not believe it to be this Court's duty



in a case of this kind to attempt to fix, or to say, what the modified tolerance shall be, except that it shall be somewhat greater. Indeed, it would seem inappropriate for the Court to substitute its lay opinion in matters of this kind for that of the trained expert, by attempting to determine the precise increase to be granted in the tolerance.

*[Regulation Unfair and Unreasonable;  
Greater Tolerance Is Administrative Matter]*

In short, as the Court views the problem here, the question may be divided into two parts: First, is the regulation fair and reasonable in its effect and, second, if not, what regulation would be fair and reasonable? The Court answers the first in the negative, and in answer to the second finds that a regulation giving some tolerance in excess of the tolerance set forth in the original regulation is required, but believes that the precise extent of such greater tolerance is an administrative matter to be determined after due hearing, etc., in the manner prescribed by the Act.

*[Administrator's Findings Not Within  
Statutory and Constitutional  
Limitations]*

Finally, the Court desires to point out that its conclusion is based upon the view that the primary object of the provisions of the Act under which this case has been brought is to protect the consumer public from adulterated and misbranded foods. We are here only concerned with foods, although the Act deals with other things. Underlying that protection is, of course, the basic idea of the promotion and preservation of health, through production and distribution of food which is not deleterious, but healthy. This, of course, presupposes that the public shall be protected from deception as to the true character of the food that is being shipped in interstate commerce. Certainly, the Government is the proper agency to surround the public with the safeguards that are necessary in order to prevent adulterated and misbranded food, but this Court believes that any regulation passed in furtherance of these basic principles exceeds the legitimate bounds of administrative regulation if it does not operate fairly and reasonably with respect to the producers or distributors of the articles involved, as well as with respect to the consumer public. It is true the Administrator

is vested with broad, discretionary authority. It is also true that, for this reason, his findings are to be accepted as conclusive if supported by substantial evidence, *provided always, however, they are within statutory and constitutional limitations. Security Adm'r v. Quaker Oats Co.*, 318 U. S. 218. In the present case, we find they are not within either limitation.

*[Rights of Grower, Canner and Consumer  
All Protected]*

Barring cases of inherently dangerous products, as for example, poisons and habit-forming drugs with respect to which of course very stringent regulations must control, when, as here, we are dealing with one of the commonest vegetables—one of the commonest foods that all of us partake of from day to day not only in season but out (thanks to the canning industry), the rights of the grower and canner of peas must be correlated to the rights of the consumer public, so that *all* are protected in a fair and reasonable manner.

*[Regulation Is in Derogation of Rights of  
Canners and Growers; Defendant Not  
Controlled by Proof at Administrative Hearing]*

In the present case it follows from what has been said that the Court finds the Administrator in promulgating that part of Regulation 51.001 here involved, fixing the alcohol-insoluble solids content of Alaska peas at not more than 23.5 per cent, has overemphasized the factor of consumer taste, and thereby has been so rigid in the regulation, in order to meet the consumer taste, that he has acted in undue derogation of the rights of the growers and canners of such peas in this general area. Whether this finding is actually supported by the weight of the credible testimony at the hearing which led up to the promulgation of the Regulation, we do not purport to determine. It is not necessary to do so, because, as heretofore explained, defendant is not controlled by what was proved or decided by that hearing, but has a right to have this Court decide the question of the Regulation's validity upon the evidence produced before it.

*[Administrator Has Only Power Given by  
Act; Other Cases Not Res Judicata]*

The Administrator does not have *unlimited power* with respect to promulgating food regulations. He has *only* such power



as is expressly given him or reasonably implied by the terms of the Act, so that the intent of the Act may be effectively carried out. Each case must be heard and decided upon its own facts. The Court is conscious of the fact that recently several canners appeared in this Court under similar charges, pleading guilty and the Court imposed fines, but the legality of the Regulation was not raised in those cases. Of course, had it been raised, and had all the features of the issues been presented as fully as in the present case, the Court would have been disposed to reach the same conclusion in

those cases that it has reached in the present case. There is no *res adjudicata* as respects the present defendant by reason of what occurred in previous cases. No defendant in a criminal case is precluded, unless by some express statutory provision or unless he has himself waived the right, from testing the validity of any statute or regulation passed pursuant thereto, when prosecuted for an alleged violation of same.

[*Defendant Not Guilty*]

Judgment will be signed in accordance with this opinion.

### TRIANGLE CANDY CO. AND BERNARD G. KENNEPOHL v. UNITED STATES

United States Circuit Court of Appeals for the Ninth Circuit. No.  
10,406. August 8, 1944. 144 F. 2d 195. 155 A. L. R. 903.

In cases involving prospective action of government officials, the word "shall" may be given a merely directory meaning if the law's purpose is the protection of the Government by guidance of its officials rather than the granting of rights to the private citizens affected.

Section 702 (b), Federal Food, Drug, and Cosmetic Act.

The case involved prosecution of the defendants for having introduced into interstate commerce candy which was adulterated under Section 402 (a) (3) and (4). The sample provision of the Act (Section 702 (b)) is not merely directory—for the guidance of the Administrator—but mandatorily gives the right to samples to the accused manufacturers unless the Administrator brings himself within the excepting regulations.

Sections 301 (a), 402 (a), 702 (b), Federal Food, Drug, and Cosmetic Act.

Section 702 (b) must have been intended to provide defendants with an opportunity for independent analysis. Providing the defendant with a portion of the sample, save in properly excepted cases, is a condition precedent to prosecution.

Sections 301 (a), 702 (b), Federal Food, Drug, and Cosmetic Act.

Haight, Trippet & Syvertson, and Lyle C. Newcomer, Los Angeles, Cal., for appellants.

Charles H. Carr, U. S. Attorney, James M. Carter and Betty Marshall Graydon, Assistant U. S. Attorneys, Los Angeles, Cal., for appellee.

Before: DENMAN, STEPHENS and HEALY, Circuit Judges.

#### [*Appeal from Conviction*]

DENMAN, Circuit Judge: This is an appeal by defendants and appellants, Triangle Candy Company, a corporation, and Bernard G. Kennepohl, from judgments rendered against them after appellants were found guilty on six counts of violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 331 (a) prohibiting "the introduction into or delivery for introduction

into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded."

#### [*Charges of Information*]

There were seven counts in the information. The adulteration charge was twofold in character in all but the first count. Alleged in each count was adulteration under 21 U. S. C. A. § 342 (a) (4), providing that a food shall be deemed adulterated "if it has



been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." In all counts save the first it was additionally alleged that there was adulteration of the candy involved under 21 U. S. C. A. § 342 (a) (3), providing that a food shall be deemed to be adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or it is otherwise unfit for food."

[*Verdict, Conviction and Fines*]

The corporate and individual defendants were each found guilty on counts II through VII. A fine of Five Hundred Dollars was imposed on the corporate defendant as to each count; its fine totaled Fifteen Hundred Dollars by virtue of the concurrency of some of the sentences. Kennepohl was fined Two Hundred and Fifty Dollars on each count, concurrency reducing the total sum to be paid to Five Hundred Dollars.

[*Contention of Appellants*]

It is the contention of the appellants that Congress made the supplying to them of part of the samples whose analysis provided the basis for the charges a condition precedent to the maintenance of a prosecution under the Act. It was stipulated at the trial that though seasonable written request was made for such samples as to each count, it was not complied with as to the samples involved in Counts III, IV, VI and VII.

Appellants' contention must be considered since, though some of the fines ran concurrently, the judgment cannot be entirely sustained if the convictions on these four counts are invalid. Kennepohl was fined Two Hundred and Fifty Dollars on Counts II and III, and the same amount on each of the other four last counts, the latter four to run concurrently with each other, and with the separate fines in Counts II and III. Since samples were furnished as to counts II and V in conformity with the statute and regulations, the judgments as to two non-concurrent fines are plainly valid with respect to the sample requirement and no finding need be made as to this question so far as Kennepohl is concerned.

However, a somewhat different situation

is presented with respect to the corporate appellant. As to it, fines of Five Hundred Dollars were levied on counts II, III and IV; and similar fines as to the last three counts, these to run concurrently with each other and with the fines on counts II, III and IV. To uphold in its entirety the judgment as to the corporate defendants, it would be necessary to find that three valid and non-concurrent fines were levied. But if the sample provision requirement be jurisdictional, not more than two of the fines can be upheld.

[*Sample Provision Requirements*]

The sample provision requirement of the Act (21 U. S. C. A. § 372. *Availability to owner of part of analysis samples:*) is as follows:

"(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Administrator shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Administrator is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of the subsection as he finds necessary for the proper administration of the provisions of this chapter."

The Administrator, in pursuance of this authorization to make reasonable exception from the sample which "shall . . . [be] provide[d]" made a regulation regarding sample provision. (S.R.A. F.D.C. 1, Rev. 1—Issued August, 1939, Revised August, 1941). Its pertinent provisions are

Regulation [2.700]. "(b) When an officer or employee collects an official sample of a food, drug, or cosmetic for analysis under the Act, he *shall collect* at least twice the quantity estimated by him to be sufficient for analysis, unless . . ." <sup>1</sup> There follows a list of seven exceptions, none of them pertinent to the facts of this case. The regulation continues

"In addition to the quantity of sample prescribed above, the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use in the trial of any case that may arise under the Act based on the sample."

---

<sup>1</sup> The government in brief and argument treats the regulations as if they did not contain this pertinent section (b).



[*No Evidence that Sample Was Twice Amount for Analysis*]

The government does not contend that any of those employed to collect samples obeyed the mandate of the regulation that they "*shall* collect at least twice the amount estimated by him to be sufficient for analysis," much less that he collected enough more for use at the trial. The most the testimony shows in this regard is that one inspector took one pound of candy as a sample (under count IV) which he "felt" was "sufficient" to supply a sample to appellant. He said nothing about its being double the amount required for analysis.

[*Regulation Set Up*]

After requiring such amounts of samples to be collected, the next subsection (c) provides:

"After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, unless . . ."

There follow two exceptions which are not pertinent here.

[*All Samples Used by Government Analyses*]

The only testimony regarding the amount of the samples left after analysis was not from any collector but from the government's chief chemist of the Los Angeles station to whom the collector sent the collected samples. He nowhere testified that double the amount deemed needed for analysis was received, plus enough to use at the trial. All he testified to is that "the reason why samples were not furnished which the candy company requested was because all the samples at the Los Angeles station were used in the course of the analyses by the chemists involved; that there was no candy left over after the analyses could be sent to them."

[*Problem Before Court*]

It is thus apparent that the government,

failing to supply the demanded samples, has not brought itself within the exceptions of the regulations created under the statute. The problem thus becomes one of the effect of such failure to obey the mandate that the Administrator "*shall* . . . provide" the samples. Was the furnishing to the owner of a portion of the sample on request, subject only to exceptions necessary to successful administration and enforcement, intended to be a mandatory prerequisite to the successful maintenance of an information based on the Act, or was the statute directing that such furnishing be made, intended as merely an administrative direction, failure to comply with which could not be complained of by those accused under the Act?

The statute, saying as it does that samples, with exceptions, *shall* be provided, is in terms mandatory. ". . . it is the language of command, a test significant, though not controlling." *Escoe v. Zerbst*, 295 U. S. 490, 493. However, in cases involving prospective action of government officials, the word "shall" may be given a merely directory meaning if the law's purpose is rather the protection of the government by guidance of its officials than the granting of rights to the private citizens affected. Thus in *Erhardt v. Schroeder*, 155 U. S. 124, a statute was held merely to be a guide to public officers which provided, in language apparently mandatory, that the collector of the port of New York should examine at least a certain proportion of shipments sent to him for examination and appraisal; and an assessment based on inspection of less than the prescribed percentage was therefore upheld. In that statute no right was granted specifically (as here) or by inference to the persons interested in the shipments.

The problem is always whether construing the statute as providing merely administrative director would impair the interest, public or private, intended to be protected. *Escoe v. Zerbst*, 295 U. S. 490. In this case a statute was held mandatory which provided for a hearing on arrest of a probationer for recommitment for violation of the terms of his probation. And see *Lyon v. Alley*, 130 U. S. 177; *French v. Edwards*, 13 Wall. 506.

[*Legislative History of Act*]

No decisions under the disputed section of the Act have been called to our attention and none has been disclosed by our search. One possible source of aid is the legislative history of § 372. The original



Food and Drug Act (34 Stat. 768; 21 U. S. C. A. 301) was passed in 1906 and did not contain any section resembling the present sample provision. Regulations promulgated under the old Act apparently gave the administrator the right to take samples and provided that "upon request one subdivision, if available, shall be delivered to the party or parties interested." (Regulations 3, Subdivision (c)). In Congress the House amended the bill for the present statute to provide that samples should be furnished only "if available." That is to say, to make the statute conform to the existing regulation. The Senate rejected the amendment and the bill was finally passed in its present form with its mandatory "shall provide."

[*Statutory Provision Held Mandatory;  
Regulation Assumed Valid*]

We hold that the provision is not merely directory—for the guidance of the Administrator—but mandatorily gives the right to samples to the accused manufacturers, unless the Administrator brings himself within the excepting regulations. This is assuming but not deciding that the present regulations providing for the giving of the sample "if any remains available" is a valid regulation where such a provision appeared in the prior regulation and its incorporation into the bill was proposed and denied.

[*Other Cases*]

The language in those cases which touch on the matter of sample apportionment as directed by statute is all to the effect that unless samples are furnished to the accused, no prosecution may be maintained. It was said in *People v. Weaver*, 116 App. Div. 594, 101 N. Y. S. 960, 965, "It is undoubtedly true that this provision as to the delivery of the duplicate sample is imperative, and that a recovery could not be had if the inspector failed to comply with it." Remarks of similar tenor may be found in *Commonwealth v. Lockhardt*, 144 Mass. 132, 10 N. E. 511, and in *People v. Bowen*, 182 N. Y. 1, 74 N. E. 489. And see *Commonwealth v. Wilson*, 89 Pittsburgh Law Journal 469.

[*English Rule*]

The English Sale of Food and Drugs Act provides that when an article is purchased with intent to submit it to the public analyst—presumably with an eye to prosecution under the act—the buyer shall notify the seller of his intention and offer to divide

the article into three parts, giving one to the seller. The English cases have held that strict compliance with the sample furnishing requirement is an indispensable condition of prosecution. *Auger v. Brown*, 36 T. L. R. 61 (1919). Additionally, the notification of intent must be in accordance with the terms of the statute. *Barnes v. Chipps*, 3 Exch. Div. 176 (1878). And each of the three subdivisions must be substantially equal and of sufficient quantity so that it is capable of being analyzed. *Lowery v. Hallard*, 1 K. B. 398 (1906).

[*Morgan Case Distinguished*]

It is urged by appellee that none of these analogies is persuasive and that the case of *United States v. Morgan*, 222 U. S. 274, demonstrates that § 372 is simply directory in its nature. The *Morgan* case arose under a section which was predecessor to the present § 335, and which provided in mandatory terms that "Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings." This section was held to be merely an administrative direction, failure to follow which did not invalidate further proceedings.

However, the section there interpreted is very different from the one involved in this case. An expressly stated ground of the *Morgan* decision was that violation of the statute would not deprive defendants of any substantial right. Failure of the Administrator to follow the Congressional directive would lead simply to a full and fair trial, without the slightest impairment of right or ability to defend against the charge. Malicious prosecution by the Administrator would remain impossible because of the requirement for filing an information or indictment. The purpose of the law was apparently to set up a common-sense procedure for the Administrator which might in some cases indicate the undesirability of instituting a formal action and in others clarify the issues for determination at the trial.

[*Provision of Sample Condition Precedent  
to Prosecution*]

The purpose of § 372 (b) is different. If those accused under the Act are not given



a portion of the sample, their power to make a complete defense is substantially curtailed. Intent is no part of the crime with which they are charged. If they have introduced the food into interstate commerce, and if it is adulterated, they are guilty, regardless of their intent or lack of knowledge as to adulteration. It may frequently happen that the single factual issue is that of adulteration. Without access to a portion of the sample, they are confronted by a government analysis of that sample which they cannot refute but at best, and with difficulty, impeach by challenging the government's method of sampling and testing.

Section 372 (b), then, must have been intended to provide defendants with an opportunity for independent analysis; and it is clear that the results of such analysis may be among the most important pieces of evidence defendants can offer in their own behalf. Deprivation of the chance to make this test, unlike the elimination of the informal hearing involved in the *Morgan* case, prejudices defendants' substantial rights. This consideration, added to the statute's mandatory wording, and the analogy of cases under other acts, lead us to the conclusion that provision of a portion of the sample, save in properly excepted cases, is a condition precedent to prosecution.

*[Certain Counts Reversed; Others  
Considered Further]*

Since, despite seasonable written request, no samples of the food involved in counts III, IV, VI, VII were furnished defendants, nor any reason offered for this failure, the convictions on these counts must be reversed. Counts II and V remain for consideration. The principal grounds of reversal urged as to these is that there was insufficient evidence to support a finding that the candy was physically adulterated with filth, or that it had been manufactured under conditions proscribed by the Act.

*[Evidence Supports Finding of  
Uncleanliness]*

As to this second ground, government inspectors testified that, at times not far removed from the date of manufacture of the candy, conditions at appellants' plant were unsanitary. They gave evidence as to the

presence of rats and cockroaches, and a showing was made that candy-making machines were left uncleaned after use. This, despite existence to contrary testimony, supports a finding of uncleanliness at the plant.

*[Evidence of Adulteration]*

It is true that the evidence of actual physical adulteration of the candy involved in counts II and V did not disclose any extremely high proportion of alien substances, and that this evidence was met by evidence of an independent analysis of other portions of the samples which disclosed no adulteration whatsoever. However, evidence was offered to the effect that in a first test an analysis of three pounds of the candy involved in count II disclosed the presence of two small rodent hairs in one of the three one-pound subdivisions; that on a later inspection some months later, and two weeks previous to the trial, there were found in three pounds of the candy a total of two rodent hairs and three insect larva and fragments.

As to count V testimony was offered tending to show that in a total of two pounds of candy sampled, seven rodent hairs were found, as well as two insect fragments, and a fragment resembling a rodent pellet. We can not say that there was no evidence supporting the judgment of the trial court. The convictions on counts II and V are sustained.

*[Judgments Affirmed in Part and Reversed  
in Part]*

Since two non-concurrent fines were validly levied on individual defendant Kennepohl, the assessed total of his Five Hundred Dollar fine remains unchanged, though the judgment is reversed as to counts III, IV, VI and VII. Since only two valid Five Hundred Dollar fines were levied on the corporate defendant Triangle Candy Company, the total fine imposed on it must be reduced from Fifteen Hundred Dollars to One Thousand Dollars.

The judgment against Kennepohl is affirmed as to Counts II and V; as to counts III, IV, VI and VII it is reversed. The judgment against Triangle Candy Company is affirmed as to counts II and V; as to counts III, IV, VI and VII it is reversed.



UNITED STATES v. ELMER J. DAILEY (DAILEY'S  
LABORATORIES)

United States District Court for the Southern District of California.  
September 7, 1944. Notices of Judgment Under the Federal  
Food, Drug, and Cosmetic Act, Drugs and Devices  
(No. 1326) Issued November 1945.

The defendant was prosecuted for having introduced into interstate commerce a drug which was misbranded because the labeling contained false therapeutic claims, and because the label failed to bear a statement as to the quantity of contents and the common or usual names of the active ingredients. In instructing the jury, the district judge declared that it was not necessary that the jury find from the evidence that the article involved was misbranded in all of the ways charged by the Government, but that the defendant must be found guilty if the jury found that the article was misbranded in any such ways.

Sections 301 (a), 502 (a), 502 (b), Federal Food, Drug, and Cosmetic Act.

The district judge further charged that the term "relief" is not of definitive connotation or entirely free from ambiguity, that in a common sense it connotes permanent removal of organic or functional disturbances as distinguished from alleviation of discomfort, and that the representation that a drug is "for" or a "treatment for" a disease is equivalent to labeling it as a cure or remedy.

Sections 201 (n), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

[Instructions to Jury]

[Court's Duty To Instruct Jury with  
Reference to Law]

LING, District Judge: It now becomes the court's duty, gentlemen, to instruct you with reference to the law that applies to this particular case.

[Nature of Proceeding]

This criminal proceeding was brought under the provision of the Federal Food, Drug, and Cosmetic Act, which was intended to prevent the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics.

[Adulterated or Misbranded Food Prohibited  
in Interstate Commerce]

The statute prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

[Unlawful Introduction of "Sugretus" in  
Interstate Commerce Charged]

In this case the government in Count I charges defendant with unlawfully introducing and delivering for introduction into interstate commerce three bottles containing an article known as "Sugretus."

[Government Alleges Products To  
Be Misbranded]

The government alleges the article to be misbranded in violation of the statute and a drug within the meaning of the statute.

Count II charges the same transaction with respect to another article known as "Sunol."

The government alleges this article to be misbranded in violation of the statute and a drug within the meaning of the statute.

[Inappropriate Labeling Alleged]

In Count II the government further alleges that the label failed to bear an accurate statement of the quantity of the contents and further that the said label failed to bear the common or usual name of the active ingredients, in violation of the statute.

[Statute Provides That Article Can Be  
Misbranded in Many Ways]

The Food, Drug, and Cosmetic Act provides that an article can be misbranded in a number of different ways. In Count I of this Information, that is with respect to the article "Sugretus," the government has confined its charges to false and misleading statements. An article can be misbranded, however, in other ways.



*[Three Ways in Which "Sugretus" Allegedly Misbranded Set Forth]*

In Count II of this Information, the government has set forth three different ways in which this article is misbranded.

First: It is alleged that the article is misbranded because of certain statements which it alleges are false and misleading.

Second: It is alleged that the article is misbranded because the label fails to bear a statement as to the quantity of contents.

Third: It is alleged that it is an article fabricated from two or more ingredients, and fails to bear a statement as to the common or usual name of each active ingredient.

*[Articles Misbranded in One of Three Ways Sufficient To Find Defendant Guilty]*

It is not necessary that you find from the evidence that the article is misbranded in all three of these ways. If you should find that the article is misbranded in any one of these three manners, then you must find the defendant guilty under Count II. If, for example, from the evidence you find that the article "Sunol" fails to bear a statement on its label of the quantity of contents, or that it is fabricated from two or more ingredients and fails to bear a statement of the common or usual name of active ingredients, then you must find the defendant guilty with respect to Count II whether or not you believe that the statements alleged to be false and misleading are in fact false and misleading.

*[Drug Misbranded in Any Particular Violates Law]*

If you find from the evidence that in any particular this drug is misbranded, then the law has been violated. It is not necessary that every misbranding be proved.

*[Fact That Articles Were Shipped in Interstate Commerce Not Disputed]*

There is no dispute that the articles set forth in the information were shipped in interstate commerce by the defendant as alleged.

It has been stipulated that the articles were introduced and shipped in interstate commerce.

*[Question of Misbranding in Violation of Statute To Be Determined by Jury]*

I, therefore, charge you that the sole

question for you to determine from the evidence in the case, is whether or not there was a misbranding in violation of the statute, as alleged by the government.

*[Harmlessness of Drug Does Not Excuse Defendant if Labeling is Found False]*

If, after hearing the evidence in this case, you reach the conclusion as to Count I that the drug or product known as "Sugretus" was harmless, that does not excuse the defendant if you find that he placed statements upon said article or drug which were false concerning curative, therapeutic, and mitigating effects of said product, as the danger and injury to the public from representations of this kind is considerable in that it induces persons frequently to rely in serious cases upon preparations without healing virtue when, but for this reliance, they would no doubt secure proper advice and treatment for the illnesses which affect them.

*[Meaning of "Relief" Set Forth]*

With respect to Count II of the Information, you are instructed that the term "relief" is not of definitive connotation or entirely free from ambiguity; in a common sense it connotes permanent removal of organic or functional disturbance as distinguished from alleviation of discomfort. The representation that an article or drug is "for" or a "treatment for" a disease is equivalent to labeling it as a cure or remedy.

*[Every Labeling Statement Found Deceptive Condemned by Statute]*

The statute under which this case has been tried condemns every statement in the labeling of the article "Sugretus," and the article "Sunol" which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements that are false. It is not difficult to choose statements that will not deceive.

*[Evidence of False Labeling Statement Should Give Verdict for Government]*

If you find from the evidence that there are any false and misleading statements in the labeling involved in this case, your verdict should be for the government, as I have stated before.



*[Determination of Whether or Not Labeling  
Statements Are Misleading]*

In determining whether or not any statements made in the labeling of "Sugretus" and "Sunol" are misleading, you should take into account, among other things, not only representations made or suggested by such statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations.

*[Evidence Which May Indicate Articles  
Misbranded]*

If you find from the evidence that there is a material weight of medical and scientific opinion contrary to any of the representations made in labeling "Sugretus" or "Sunol," you may find that said articles are misbranded.

If you find that the circular introduced in evidence in this case, and contained in the package admitted to have been shipped in interstate commerce by the defendant, as alleged in Count I, contains statements describing the curative, therapeutic or mitigating effects of the article or drug, and find that such statements are likely to mislead in any particular, you should find the defendant guilty of misbranding on Count I.

*[Directions for Examination of Language  
Used in Labels and Circulars]*

What these labels and circular mean, you are to test by taking the language of each of them and imparting to that language the meaning of the words singly and together that would be conveyed to you as ordinary men, not as men who are skilled in medical, chemical, or pharmaceutical science capable of making nice distinctions or nice discriminations, but rather the meaning that comes to you as ordinary men unskilled, but seeking, we will assume, some sort of remedy or remedial help from the afflictions that flesh is heir to. Now, in that connection, you should examine the language used in the light of the purpose of this law, which is to protect human kind against the consequence of human weakness, or human failing, or human credulity, or the disposition to believe, or of human gullibility. You should examine it in the light of the disposition of the ordinary human kind to wish to believe in the potency of remedial agents to relieve them of ills from which they are actually or conceivably suffering.

*[Labeling Statements To Be Viewed in  
Light of Purpose of Food and  
Drug Act]*

Under the Food and Drug Act the term "drug" includes any substance or mixture of substances intended to be used for the cure, mitigation or prevention of diseases of mankind. The aim of the Act is to prevent indirection and ambiguity in the labeling of drugs, as well as to prevent statements which are literally false. It is not difficult to choose statements, designs, or devices concerning the curative, therapeutic or mitigating effect of any article or drug which will not deceive. Those which are ambiguous or likely to mislead should be read favorably to the accomplishment of the purposes of the Act, and if you find the labels and circular used by the defendant, Elmer J. Dailey, describing the curative, therapeutic and mitigating effect of the articles or drugs "Sugretus" and "Sunol" contain statements that are likely to mislead, in any particular, you should find the defendant guilty of misbranding.

Of course, if you do not so find, you should find the defendant not guilty.

*[Opinion Evidence Not Binding Upon Jury]*

Witnesses, those who are supposed to know more than the ordinary person about such subjects, such as chemists and physicians, have been permitted to give their opinions as to various matters. Opinion evidence is not binding upon you, but should be considered in connection with all other evidence in this case. Should you believe it, you may accept and follow it. By an opinion, I mean a statement or a conclusion arrived at by the witness from experience or from knowledge, as distinguished from testimony concerning the direct fact.

*[Distinction Between Statement of Fact  
and Opinion]*

That is, I might say that this building was constructed of brick. That would be a statement of fact. If I would say it was worth twenty thousand or a hundred thousand dollars, that would merely be my opinion.

*[Value of Opinion Evidence To Be Decided  
by Jury]*

You are the sole judges of the value of opinion evidence. Of course, an opinion is worthless unless it is the honest opinion of the man who states it. If you deem it is his honest opinion, then its value depends upon



how much he knows about the subject concerning which he is testifying. If he is fairly experienced, fairly grounded in his subject, if his opinion is the result of mature reflection, if he is a man of strong logical intellect, his opinion would be entitled to great value. If, on the other hand, he is incapable of logical thinking, or if he is not well grounded in his subject, nor familiar with the facts upon which his conclusion is assumed to be based, then, of course, his opinion would be of little or no value; and it is for you to decide what value you will give to the opinion evidence that you have heard.

*[Proof that Defendant Intentionally Misbranded Articles Immaterial]*

It is not necessary for the government to prove the defendant intentionally misbranded the articles in any particular. Intent is immaterial in a charge of misbranding as is charged in this case.

*[Verdict To Be Rendered in Accordance With Evidence]*

So, if you find from the evidence that the labels and circular contained false and misleading statements in any particular, then you must render your verdict accordingly.

*[Matters To Be Considered in Weighing Testimony of Witnesses]*

Now, a great deal of the evidence of the witnesses who have testified concerning their own ailments is in the nature of opinion evidence. Those witnesses who testified that they had well-known, easily discernible diseases, or easily-told diseases, I will say, such as headaches and constipation, or something of that sort, of course, there will be very little reason to doubt that they knew what they had. But if one testified that he thought he had some more obscure disease, more difficult to diagnose, and his diagnosis of what he had depended entirely upon his own opinion, and he was unable to make such a diagnosis, his opinion would be of very little value. Those are matters for you to take into consideration in weighing the testimony of the witnesses.

*[Credibility of Witnesses To Be Considered]*

You are the sole judges of the facts of this case, also of the credibility of each and every witness who has testified before you, and the weight that you will give his testimony. In determining the credibility of any witness you have a right to take into consideration his or her manner and appear-

ance while giving his or her testimony, his or her means of knowledge of the facts to which he or she has testified; any interest or motive he or she may have for his or her testimony, if shown, and the probability or improbability of the truth of his or her statements when measured in connection with all other evidence in the case. If you believe that any witness has wilfully sworn falsely as to any material fact, then you have a right to wholly disregard the testimony of such witness, except insofar as the same may be corroborated by other credible evidence or by facts and circumstances proven or admitted in the case.

*[Government Must Prove Truth of Material Allegations Before Defendant Can Be Convicted]*

In order to convict the defendant of the crime charged in the indictment, it is incumbent upon the government to prove to you beyond a reasonable doubt and to a moral certainty the truth of each and every material allegation of the indictment. The law raises no presumption against a defendant, but every presumption of law is in favor of his innocence.

*[Definition of Reasonable Doubt]*

A reasonable doubt as applied to evidence in criminal cases, is such a doubt as you may entertain as reasonable men after a thorough review and consideration of all the evidence, a doubt for which a reason arising from the evidence, or from the want of evidence, exists. It is not, however, a fanciful conjecture of the mind, nor the mere possibility of a doubt, but it is a substantial, well-founded doubt. It is that state of the case which, after a full and fair review of all the evidence, leaves the mind of a juror in such condition that he cannot say he feels an abiding conviction to a moral certainty of the guilt of the accused. It is an actual, sincere mental hesitation caused by insufficient or unsatisfactory evidence.

*[Proof of Guilt Beyond Reasonable Doubt Sufficient]*

While it is true that the government is required to prove the guilt of the defendants beyond a reasonable doubt, it is not required to prove their guilt to a mathematical certainty. All that the court and the jury can act upon is belief to a moral certainty and beyond a reasonable doubt.

*[Determination of Guilty and Not Guilty Verdict]*

Now, if, after fully and fairly considering all of the evidence in this case you enter-



tain such a reasonable doubt as I have defined as to the guilt or innocence of this defendant, then it becomes your duty to resolve that doubt in favor of the defendant and to return a verdict of not guilty. On the other hand, if, after so considering all of the evidence in the case you are satisfied beyond a reasonable doubt and to a moral certainty that the defendant has committed the acts as charged and constituting the crime set forth in the Information, then it becomes your duty to render a verdict of guilty.

*[Procedure After Retiring To Jury Room  
Set Forth]*

After you retire to the jury room you will select one of your number to act as

foreman, and you will proceed with your deliberation. After you have agreed upon a verdict you will have it signed by your foreman and return it to open court. And any verdict rendered, of course, will be the unanimous verdict of the jury.

*[Form of Verdict To Be Prepared for  
Guidance]*

A form of verdict has been prepared for your guidance.

[The jury thereupon retired and, after due deliberation, returned a verdict of guilty. On September 15, 1944, the court imposed a fine of \$250 on count 1 and suspended the imposition of sentence on count 2, placing the defendant on probation for 5 years.]

---

**JOSEPH v. UNITED STATES**

United States Circuit Court of Appeals for the Ninth Circuit. No. 10,631.  
September 21, 1944. 145 F. 2d 74.  
Certiorari denied, 323 U. S. 776 (1944).

In the absence of exceptions taken in the trial court, no point is raised for decision on appeal.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

The decision on a motion for a new trial is not reviewable in any event.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

The case involved prosecution of the defendant for having introduced adulterated food into interstate commerce. Defendant stipulated, among other things, that the shipments alleged in the information were food. Defendant subsequently changed attorneys, and, on the eve of the trial, moved to be relieved from the stipulation on the ground that the product shipped was not to be used as food without further processing. The motion was denied and no exception was taken. The proper way to have raised the question in the trial court as to whether the stipulation could be considered as sufficient evidence of the crime, without further proof of the *corpus delicti*, would have been by motion for a directed verdict. Since none was made, the question was not before the Circuit Court of Appeals.

Sections 201 (f), 301 (a), 303 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Moreover, the stipulation covered all the facts necessary to show the commission of an offense and was sufficient without additional evidence.

Section 201 (f), Federal Food, Drug, and Cosmetic Act.

Strother P. Walton and Ralph Robinson, Fresno, Cal., for appellant.

Charles H. Carr, U. S. Attorney; James M. Carter and Mildred L. Kluckhorn, Assistants and U. S. Attorneys; Los Angeles, Cal., for appellee.

Before: WILBUR, DENMAN, and MATHEWS, Circuit Judges.

*[Denial of Motion To Be Relieved from  
Stipulation Assigned as Error]*

WILBUR, Circuit Judge: Appellant Joseph

was charged by information with a violation of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. § 321 (f)). The information contains two counts, one charging a



shipment of contaminated food on January 25, 1943, and the second charging a similar shipment on December 30, 1942. The case was tried before a jury and judgment of conviction on the verdict was rendered on both counts. Appellant was sentenced to a fine of \$250 on the first count and, on the second count imposition of sentence was suspended for a year during which period he was placed on probation. The appellant entered into a stipulation of facts, with the government in which, among other things, it was stipulated that the shipments alleged in the information were food. On the eve of the trial the appellant changed attorneys and on the day of the trial, November 10, 1943, without previous notice to the government, appellant made a motion that he be relieved from the stipulation on the ground that the product shipped was not to be used as food without further processing. The motion was denied and no exception taken. The denial of this motion is assigned as error.

[*Motion for New Trial*]

The same question was raised on a motion for new trial. A further ground for the motion for new trial was that a government witness had been seen conversing with a juror.

[*Decision Below Affirmed*]

In the absence of exceptions taken in the trial court no point is raised for decision on appeal. Decision on motion for new trial is not reviewable in any event. The appellant argues that there was no evidence on the second count except the stipulation and therefore it cannot be considered as sufficient evidence of the crime without further proof of the *corpus delicti*. The proper way to raise this question in the lower court would be by motion for a directed verdict. None was made and consequently the question is not before us. Moreover, the stipulation covered all the facts necessary to show the commission of an offense and was sufficient without additional evidence.

Affirmed.

**Concurring Opinion**

DENMAN, Circuit Judge (concurring in the result, but dissenting from decision that in a criminal appeal, in the absence of a motion for a directed verdict, no question can be before the appellate court): I dissent from the refusal on technical grounds to consider the cogently presented contention of appellant that the stipulation of the otherwise

unproved fact, namely, that the shipment was a food, a fact necessary for conviction on both counts, was in the nature of a confession or admission and required further proof of the *corpus delicti*. The contention is an important one, seemingly of novel import.

The statement that "Moreover, the stipulation covered all the facts necessary to show the commission of an offense and was sufficient without additional evidence," in no way warrants the refusal to consider appellant's contention, for, if it be correct, the stipulation is nonetheless a confession requiring corroboration because it contains all the elements of the crime.

Where, as here, a motion is made and denied though no exception is taken, the majority opinion's statement that "In the absence of exceptions taken in the trial court no point is raised for decision on appeal" is a return to the technical denial of appellate justice of *Sherwin v. United States*, 9 Cir., 112 F. 2d 503, 504, despite the reversal of that case in 312 U. S. 654, 61 S. Ct. 618, 85 L. Ed. 1104. There the Supreme Court instructed us to consider the contention of the insufficiency of the evidence to sustain the verdict, though there was no exception to the denial of the motion to direct a verdict or to dismiss—an absurd order for the Supreme Court to make if, in the absence of an exception, the bill showed no point raised for decision on appeal.

Likewise with regard to the failure of the bill of exceptions to show that appellant sought a directed verdict. I am ignoring the fact that the minutes of the trial court, appearing in the transcript, show that such a motion was made and that an exception was taken. It is not the law of this circuit that the question of the sufficiency of the evidence to sustain the verdict cannot be before us in the absence of such a motion. The repeated holdings of this court are that it will consider the merits of a contention that there is no evidence to support the conviction, even though there be no motion for a directed verdict on that ground.

In *Bailey v. United States*, 9 Cir., 13 F. 2d 325, 327, Judge Rudkin's opinion established the law for this Circuit to be:

"We are, of course, aware that there was no request for an instructed verdict at the close of the testimony, as suggested by counsel; but if there is no competent testimony to support the verdict of guilty, and more especially if it appears affirmatively that no crime has in fact been committed, the right and duty of this court



to order a reversal is not open to question.

"The judgment of the court below is therefore reversed, and the cause is remanded for a new trial."

In that case the evidence was reviewed and the lower court was reversed.

The *Bailey* case was followed in *Marco v. United States*, 9 Cir., 26 F. 2d 315, 316, where, without a motion for a directed verdict, the evidence was reviewed and the conviction sustained, the court holding:

"The sufficiency of the testimony to support the verdict was not raised at the conclusion of all the testimony in the court below, and for that reason the question is not properly before us for review. Under such circumstances courts will only look into the record far enough to see that there has been no miscarriage of justice, or that there is some testimony tending to support the verdict."

The court in the first case was constituted of Judges Gilbert, Hunt and Rudkin; in the second case of Judges Gilbert, Rudkin and Dietrich.<sup>1</sup>

However, in this appeal the contention the court refuses to consider does not require a review of the evidence, for the appellee's brief admits as to both counts on which appellant was held guilty that in the absence of the stipulation there was no proof of the necessary fact that the shipment in interstate commerce was a food. Concerning the second count, the necessary proof of contamination of the article shipped in interstate commerce does not appear other than in the stipulation. Appellant therefore is refused the consideration of what is purely a question of law which, if he be correct, has been decided below in a manner to constitute what this court has repeatedly described as "a miscarriage of justice," which it is our duty to consider.

The position of appellant, in effect, is as follows: If appellant, after information filed but before trial, had met the United States

Attorney and given him a signed confession that his interstate shipments were foods and were contaminated and later at the trial the United States Attorney had offered the confession in evidence, no crime was proved and no conviction could be had unless independent proof was made of the food nature of the shipment and its contamination. *Gordnier v. United States*, 9 Cir., 261 F. 910, 911; *Ryan v. United States*, 8 Cir., 99 F. 2d 864; *Gulotta v. United States*, 8 Cir., 113 F. 2d 683; *Anderson v. United States*, 6 Cir., 124 F. 2d 58. Hence, appellant's contention continues, the written confession of his agent, his counsel, contained in the stipulation, can have no higher value than the written confession of the agent's principal, the appellant.

Appellee nowhere meets this contention with any case in which the question of the necessity of proof of the *corpus delicti* is raised. Appellee has cited no criminal case and our search has revealed none in which the effect of stipulations made before trial has been considered. It seems a question of novel import.

In my opinion, such a stipulation, though in effect it be a confession, is not an extrajudicial act. The attorney for appellant's litigation is not a mere agent when he enters into a stipulation with the government's attorney. The attorneys of both parties are officers of the court and, since the making of the stipulation in existing litigation is within the functions of the appellant's attorney's office, the confession appearing in the stipulation is an action for the court itself and in that sense a judicial act. Though, before trial, its effect is no different in establishing the fact than such a stipulation made in the course of the trial, or, if the defendant took the stand, his statement there that the shipment was a food.

The judgment should have been affirmed on the grounds here stated.

---

<sup>1</sup> Since the instant case was decided, the principle of the *Bailey* and *Marco* cases has been reaffirmed in *Giles v. United States*, 9 Cir., 144 F. 2d 860. The court, constituted of Judges Denman, Stephens and Healy, consid-

ered an assigned error, though no objection was made or exception taken, "far enough to see that there has been no miscarriage of justice."



## UNITED STATES v. GERBER PRODUCTS CO.

United States District Court for the Western District of Michigan.  
November 20, 1944.

Notices of Judgment under the Federal Food, Drug, and Cosmetic Act,  
Foods (No. 7808) Issued January 1946.

The defendant was prosecuted for having introduced into interstate commerce strained peaches which were adulterated under Section 402 (a) (3). The district judge instructed the jury that the words "filthy, putrid, or decomposed," as used in the section, are to be construed in their usual and ordinary meaning—they are not confined to any scientific or medical definitions.

Sections 301 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The district judge further declared that it was not the intention of Congress to include as a criminal offense the presence of filthy, putrid, or decomposed matter in such infinitesimal and inconsequential quantities as even the highest degree of care would not eliminate, but that the presence of worm heads, etc., in such a substantial quantity that such contamination should have been discovered and eliminated would constitute adulteration within the definition of the Act.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The jury was also charged that if it found beyond a reasonable doubt that the food in question was filthy or putrid, or contained decomposed substances within the usual and ordinary meaning of those words, it was not essential to a verdict of guilty that the jury should also find that the food was poisonous or deleterious to health or was otherwise unfit for food.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

**[Instructions to Jury]**  
*[Two Separate Charges To Be  
Considered]*

RAYMOND, District Judge: Members of the Jury, the information, which is the formal complaint upon which the respondent is on trial in this case, contains two counts. This means that the respondent, the Gerber Products Company, is here on trial before you upon two separate and distinct charges, and, as I shall later instruct you, it will be within your province, as you may view the evidence, to find the respondent guilty upon both counts of the information, or not guilty upon both counts of the information, or guilty upon one count and not guilty upon the other.

*[Alleged Violated Sections Set Forth]*

The information is based upon Sec. 331 (a) and Sec. 342 of Title XXI of the United States Code. Sec. 331 (a) prohibits the introduction or delivery for introduction into interstate commerce of any food that is adulterated. Sec. 342 provides that food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food. This section, enacted

in the interests of the public health, clearly prohibits shipment in interstate commerce of any food which contains filthy, putrid or decomposed matter.

*[Count I Discussed]*

The information filed in this case charges in Count 1 substantially as follows: That the Gerber Products Company, a corporation, of Fremont, Michigan, did on or about January 2nd, 1943, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully introduce and deliver for introduction into interstate commerce from Fremont, Michigan, to St. Paul, Minnesota, consigned to Gerber Products Company, a certain consignment, to-wit, a number of cans, each can containing a food within the meaning of the Federal Food, Drug, and Cosmetic Act; and that said food when introduced and delivered for introduction into interstate commerce was then and there adulterated within the meaning of the Act of Congress, in that it consisted in whole or in part of a filthy and decomposed substance, by reason of the presence in said food of moldy peach pulp, worm fragments and insect fragments.



[*Count II Discussed*]

Count 2 charges that this same respondent did on or about the 12th day of September, in the year 1942, in violation of this same act, unlawfully introduce and deliver for introduction into interstate commerce, from Fremont, Michigan, to Los Angeles, California, consigned to Gerber Products Company, a certain consignment, to-wit, a number of cans, each can containing a food, and that said food when introduced and delivered for introduction into interstate commerce was then and there adulterated within the meaning of the Act of Congress, in that it consisted in whole or in part of a filthy or decomposed substance, by reason of the presence in said food of moldy peach pulp, worm fragments and insect fragments. Those are the two charges upon which this respondent is charged with guilt.

[*Burden on Government*]

Now the law presumes this respondent to be innocent of the offenses charged against it in the information, and throws around it the protection of that presumption; and the burden rests upon the government to establish by evidence and beyond a reasonable doubt each and every essential element of the offenses charged, and to negative each and every reasonable hypothesis of respondent's innocence. This burden remains upon the government throughout the case, and there is no burden resting upon the respondent to establish its innocence. It will be your duty therefore, as jurors, to commence your deliberations with the presumption of its innocence uppermost in your minds, and to continue your deliberations with that presumption uppermost in your minds until you and each of you has become convinced of the respondent's guilt by the evidence in the case, and beyond a reasonable doubt.

[*Reasonable Doubt Defined*]

By a reasonable doubt is meant exactly what the term implies, namely, a doubt for which there is a reason. The reasonable doubt which will prevent a juror from voting for conviction is and it must be a real and a substantial doubt, as distinguished from a merely possible or imaginary one; it must be a fair and an honest doubt, as distinguished from a merely captious or capricious one. It must be a doubt which grows out of the evidence which has been offered and received in the case, and one that is based upon reason and common

sense, and not a doubt which grows out of or is based upon bias, or prejudice, or sympathy.

[*Establishment of Reasonable Doubt*]

If any juror has such a reasonable doubt as to the guilt of the respondent, you will have no right to vote for conviction. On the other hand, no juror has the right arbitrarily and without reason to say that he has a doubt, and thereupon refuse to convict. If you have such a reasonable doubt as to the guilt of respondent, it will be your duty to acquit it. On the other hand, if you have no such reasonable doubt, it will be equally your duty to convict the respondent.

[*Jury Is Sole Judge of Facts*]

Now, during the course of this charge I shall state to you in substance and in a general way the principal claims of the government and of the respondent. I do not intend to state all of their claims, but only the substance thereof, so that you may know generally what the matters are that are principally in dispute. It will be for you to remember the claims and all of them, from the testimony and from the statements and arguments of counsel, and you will understand that in stating them, the Court does not intend to state them as the Court's own views of what the testimony shows, because that is a matter for you, the jury, exclusively to determine. You are the sole judges of the credibility of the witnesses, and of the weight which should be given to the testimony upon any point in issue, and it is for you and you alone to determine finally what the facts in this case are, entirely uncontrolled by any comment which the Court may make, and to apply to those facts the law as the Court will give it to you in these instructions.

[*No Dispute That Goods Were Introduced in Interstate Commerce*]

There are one or two issues that have been eliminated from the case by agreement and stipulations of counsel. It has been agreed between the government and the respondent that the contents of the shipments to St. Paul and to Los Angeles are properly classed as food within the meaning of the statute, and that the shipments were made by the respondent from Fremont, Michigan, to those cities as alleged in the information. These goods were, therefore, introduced into interstate commerce by the respondent.



*[Principal Question Before Jury  
Involves Adulteration]*

The principal question for your consideration and determination is whether or not the shipments of strained peaches which were made from Fremont to St. Paul and to Los Angeles on January 2nd, 1943 and on September 12th, 1942 respectively, contained strained peaches which were adulterated within the meaning of the statute. Now I shall not attempt to define the word "adulterated" to you, for the reason that the definition is contained within the Act of Congress in the following language: "Food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food." The language is clear.

*[Criminal Intent Not Involved in This Case]*

You are instructed that the words "filthy, putrid and decomposed" as used in the Act of Congress are to be construed and applied by you to the evidence in this case in their usual and ordinary meanings. They are not confined to any scientific or medical definitions. You are instructed that the element of criminal intent which is present in many cases is in no way involved in this case. Even the unintentional introduction of adulterated foods into interstate commerce is forbidden by this statute which I have read to you.

*[Exercise of Reasonable Care in Production  
of Strained Peaches Could Eliminate  
Foreign Substances]*

You are instructed that to warrant a verdict of guilty the government must prove beyond a reasonable doubt that the strained peaches in these shipments contained filthy, putrid or decomposed substances in substantial amounts. The respondent urges that it is impossible in practice in the production and canning of strained peaches to entirely eliminate all such contamination at all times. The government claims, however, that these objectionable elements were present in the shipments here involved in such substantial quantities that it was entirely within the power of the respondent by the exercise of reasonable care to have eliminated these foreign substances entirely, and that respondent does, in fact, when it exercises proper care, accomplish that result.

*[Presence of Substantial Quantity of  
Decomposed Substance in Strained  
Peaches Constitutes Adulteration]*

You are instructed, however, that it was

not the intention of Congress to include as a criminal offense the presence of filthy, putrid or decomposed matter in such infinitesimal and inconsequential quantities as even the highest degree of care could not eliminate. You are instructed, however, that the presence of worm heads, worm legs, portions of worm bodies, fragments, fly eggs, mites and rotted peach tissue with mold in such a substantial quantity that such contamination should have been discovered and eliminated would constitute adulteration within the definition of the statute.

*[Act Violated Even If Product Not  
Deleterious]*

If you do find beyond a reasonable doubt that the food in question was filthy or putrid, or that it contained decomposed substances within the usual and ordinary meaning of those words, you are instructed that it is not essential to a verdict of guilty that you shall also find that the contents of the cans were poisonous or were deleterious to health or were otherwise unfit for food. It is for you to determine from the evidence in the case what the facts are with reference to the condition of the food in question at the time it was introduced into interstate commerce, and having determined those facts to reach your conclusion as to whether or not the food was adulterated within the meaning of that word as defined in the statute.

*[Basis for "Not Guilty" Verdict]*

Of course, if you believe from the evidence that it was practically impossible in actual practice to free the strained peaches entirely and at all times from the presence of rotten peach tissue, mold, worm heads, worm legs, portions of worm bodies, fragments, fly eggs and mites, and that such contamination was present in the shipments here under consideration in such infinitesimal and microscopic quantities that you do not regard it as filthy, putrid or decomposed in the usual, natural and practical sense of those words, then your verdict should be for the respondent of "Not guilty." On the other hand, if you find beyond a reasonable doubt, as I have defined that term, that the strained peaches here involved contained substantial amounts of these foreign substances, then your verdict should be "guilty as charged."

*[Rights of Jury Set Forth]*

You are the sole judges of the credibility of the witnesses. It is for you and you



alone to determine who has told the truth and where the truth lies. You will give to the testimony of each and every witness such weight and credence as you believe it is entitled to, and in weighing and measuring the testimony of each witness you have the right to take into consideration his appearance upon the witness stand, the reasonableness or unreasonableness of the story which he has told. You have a right to take into consideration any motive which he may have had for testifying falsely. You have a right to take into consideration any interest which he may have in this prosecution or its outcome. You have no right for trivial reasons to find that any witness has testified falsely, and it will be your duty if possible to harmonize and reconcile the testimony of the witnesses in this case upon the theory and basis that each and every witness has attempted to tell the truth. If you are unable to do so, it will then be your duty to determine the testimony which is true and that which is untrue, and when you have made that determination, you will discard and disregard the testimony which you find to be untrue and reach a verdict based upon all the evidence in the case which under all the circumstances you believe to be true.

*[Importance of Case Stressed]*

Now this case is important. All criminal cases, of course, are important. It is important that no innocent respondent should be convicted. It is important that due process of law should be at all times observed and that no one shall be convicted by a jury until that jury, after a fair, candid and impartial scrutiny of the testimony has reached the conclusion therefrom under the law as I have given it to you that the respondent is guilty beyond a reasonable

doubt. Upon having reached that conclusion, however, if you do so, then the interest of the public intervenes, and it is of the utmost importance that the law should be vindicated, and that offenders against the majesty of the law should be made to answer for their crimes. In the performance of that duty there is no place for prejudice, passion or sympathy. You should go forward to your duty, so that you will see nothing except the law, the evidence, and your duty, and you should enter upon the consideration of this case with those facts uppermost in your minds.

*[Respondent May Be Convicted upon Both Counts]*

As I have indicated, you may convict the respondent upon both counts of the information. You may convict it upon one count and acquit upon the other; or you may acquit it upon both counts. If you find from all the evidence and beyond a reasonable doubt, as I have defined it, that the food was adulterated within the definition contained in the statute at the time each of the shipments were introduced into interstate commerce, then your verdict should be "Guilty as charged." If you find that it was not so adulterated, then your verdict should be "We find the respondent not guilty." If you find that there was adulteration as to one of the shipments and not as to the other, you will indicate by your verdict the count upon which you acquit and the count upon which you convict, bearing in mind that the first count sets forth the shipment of January 2nd, 1943, from Fremont to St. Paul, and that the second count sets forth the shipment from Fremont to Los Angeles, on September 12th, 1942.

[On November 20, 1944, the jury, after due deliberation, returned a verdict of not guilty.]

---



## UNITED STATES v. COMMONWEALTH BREWING CORPORATION AND LEO KAUFMAN

United States District Court for the District of Massachusetts. May 22, 1945.  
 Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act,  
 Foods (No. 7926) Issued March 1946.

The defendants were prosecuted for having introduced into interstate commerce beer and ale which were adulterated under Section 402 (a) (2) since they contained an added poisonous or deleterious substance, fluorine, which was unsafe inasmuch as it was not required in the production of the articles. In charging the jury, the district judge declared that it was entirely unimportant and irrelevant how much fluorine was added; the issue was whether fluorine in some form was added.

Sections 301 (a), 402 (a), 406 (a), Federal Food, Drug, and Cosmetic Act.

The quantity of the alleged poisonous substance would be important under Section 402 (a) (1), but under Section 402 (a) (2) quantity is irrelevant and the only question involved is whether it was an added deleterious substance.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

It was of no importance that no evidence had been introduced to show that someone drank the beer and was harmed; the question was not whether the beer was harmful but whether the fluorine, if it was added, was harmful and poisonous.

Sections 301 (a), 402 (a), 406 (a), Federal Food, Drug, and Cosmetic Act.

The jury was charged that if the Government proved beyond a reasonable doubt that the fluorine was a deleterious substance and was not required and could be avoided by good manufacturing practice, the jury would be warranted in finding that the beer was unsafe.

Sections 301 (a), 402 (a), 406 (a), Federal Food, Drug, and Cosmetic Act.

### [Instructions to Jury]

#### [*The Jury Must Decide Facts*]

FORD, District Judge: Before I explain to you what a reasonable doubt is,—it has been explained to you in more or less detail by one of the counsel—before I come to that, gentlemen, I want to say to you what our different provinces are. Counsel has explained them to you.

The facts are for you. You, as has been said by counsel, are the sole arbiters of the facts, to decide the facts. I give you the law, and you must take your law from me. If I make an error with respect to the applicable principles of law, then of course I can be corrected by a higher court. The credibility of the witnesses is for you. Do you believe the witnesses? Do you believe them in whole or do you believe them in part? The credibility of the witnesses is for you, as I have said.

Now, when you pass upon the credibility of a witness decide whether or not he is telling the truth, deciding what part, if any, of

the evidence is credible, then of course you can take into consideration his appearance on the stand, the manner in which he answered the questions, whether he has any bias or prejudice with respect to the case itself, and generally decide how much of his evidence—*any* witness in *any* case—how much of his evidence you will believe in looking at him, hearing him. That is your province exclusively.

#### [*Defendant's Failure To Testify*]

There is one other principle here that is applicable. Failure of the defendant here, the individual defendant, Kaufman, to take the stand and testify in his behalf, raises no presumption against him. No prejudice must arise against him for not taking the stand. That applicable rule and principle is expressed in a United States case which reads as follows: "In the trial of all indictments against persons charged with the commission of crimes in the United States Court, the person so charged shall of his own re-



quest be a competent witness and his failure to make such request shall not create any presumption against him." That is, he is not obliged to testify, gentlemen, unless he desires to. He may testify if he wishes, and if he does not he cannot be prejudiced because of that fact.

*[Proof Beyond a Reasonable Doubt]*

Now, I said to you that the burden is upon the Government to prove every essential element of the offense charged beyond a reasonable doubt, and later I shall go on and tell you what the Government charges, what the essential elements of the charges are in detail.

Counsel has described to you, has defined what a reasonable doubt is, proof beyond a reasonable doubt, and I like to read what has been said by, if not the Supreme Court, one of the other courts, in deciding what a reasonable doubt is, the quantum of proof, how much proof the Government must adduce before you would be warranted in finding a defendant in any case guilty. "Reasonable doubt is such a doubt as would affect the mind and judgment of the ordinarily reasonable and prudent person in making decisions on important matters." Proof beyond a reasonable doubt has been defined correctly as "not beyond all possible or imaginary doubt, \* \* \* but such proof as precludes every reasonable hypothesis except that which it tends to support. It is proof to a moral certainty as distinguished from an absolute certainty."

It is said in other cases and at other times that it is proof beyond a probability but not an absolute certainty.

"The term 'reasonable doubt' means a doubt which is substantial, not shadowy. It does not mean a doubt born of reluctance on the part of a juror to perform an unpleasant duty or a doubt arising out of sympathy for a defendant or out of anything other than a candid consideration of all the evidence presented. While it is a requisite to a verdict of guilty that the prosecution prove the guilt of the accused beyond reasonable doubt, the doubt to the benefit whereof the accused is entitled must be the doubt that a rational sensible person may fairly entertain; not the doubt of a vacillating mind that has not the moral courage to decide."

*[Indictment]*

Now, gentlemen, with those principles in mind, applicable to all criminal cases—and in all criminal cases the duty is imposed upon the Court to lay down those principles

before proceeding to the charge, and it would be error on the part of the Court if those instructions were not presented to you—this brings us to the present indictment, Mr. Foreman and gentlemen, and the indictment with which we are concerned here is an indictment in eight counts, eight different shipments, and each count charging a separate shipment in violation of Section 301 (a) of the Food, Drug, and Cosmetic Act. The indictment simply charges that these defendants introduced and delivered and caused to be introduced and delivered for introduction into interstate commerce the aforesaid certain food which was then and there adulterated within the meaning of said Act of Congress, and then defines the Act which I shall refer to in more or less detail. This is the charge in the indictment, and here is where you take it from, the indictment, the charge made in accordance with the applicable section of the statute. Here is where we find the essential elements of the charge which I shall point out to you and which the Government is required to prove beyond a reasonable doubt, in that "it contained an added poison or deleterious poison, fluorine, which was unsafe within the meaning of the statute," the particular section of the statute, "since it was a substance not required in the production of this beer and could have been avoided by good manufacturing practice."

*[History of Food and Drug Act]*

Now, we all know it generally, but there is a history back of the Food, Drug, and Cosmetic Act. I think it was shortly after the turn of the century some time if I am correct, but I am sufficiently correct in saying, in 1906 I know, the Food and Drug Act was passed by Congress, and at that time Congress wanted to scrape out the evils that were present in the United States of America, with respect to the adulteration of foods, the presence of poisonous and deleterious and impure substances in food, and also to protect the public against fraud with respect to food products, misbranding by having labels misbranded where the public were being cheated.

In 1906 Congress passed the Pure Food and Drug Act and with various amendments we come down to the Act, I think the date of this Act is 1938. It is now called the "Food, Drug, and Cosmetic Act. Well, "pure" is not in there, it is called the "Food, Drug, and Cosmetic Act." We always find what the name of the Act is in



the Act itself, and this designates it. It may give you some idea in the sections of this statute what Congress was going to do, in the sections where it defined an adulterated food. It said, "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substances which may render it injurious to health." I will have occasion to refer specifically to this question later. And note this also; "but in case the substance is not an added substance," and it becomes here a question of an added substance. Congress provided in this particular section, (a) (1) of 342 of 21 U. S. C. A.—that is not the exact section of the Act itself, I am reading Section 402—Congress said, "In case the substance is not an added substance"—that is not our case, as I will point out to you later, "but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health." And the clause with which we are here concerned, the section of the statute under which this prosecution is brought, refers to food which may contain any added poisonous or added deleterious substance. Here we have the added aspect of substance where we did not have it in the first section which is "unsafe within the meaning of Section 346," because that is the section of the statute as I say under which this prosecution proceeds.

Then it provides a section with respect to the presence of filthy, putrid or decomposed substances in the food, and then protected the public by the passage of this statute which Congress made as to food under unsanitary conditions so that the food would be rendered contaminated.

I read those sections to you to show the purpose that Congress had in passing these food and drug acts. This act itself is denominated "Food, Drug and Cosmetics." It went along and protected the public in the same direction with reference to the adulteration and misbranding of cosmetics as well as food and drugs.

*[Pertinent Provision of Act Involved]*

Now, the section of the Act which the defendants are charged with violating here among those sections that I have just read is Section 301 of the Act. Section 301 of the Act prohibits the introduction or delivery into interstate commerce of any food that is adulterated, and since Congress here and the Act itself have defined food as

meaning articles used for food or drink for man or other animals, the beer with which we are concerned here is a food.

Congress further defined the meaning of "adulterated food" as follows in Section 402, Subdivision (2), of the Act: "A food shall be adulterated: If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406," and Section 406 of the Act with which we are concerned here said that any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of this clause I have just read to you.

*[Liability of Individual Defendant]*

With these pertinent clauses of the food and drug act in mind, we return to the indictment, as I said to you before, and find out what the Government charges and what are the essential elements that the Government must prove. The essential elements of the charge that the Government must prove beyond a reasonable doubt in order to warrant a conviction of the defendant corporation and the defendant Kaufman are: First, the Government charges, as I have read to you from the indictment, these defendants with making eight separate interstate shipments of beer. With respect to the corporation it is admitted here that the corporation actually shipped the beer. With respect to the defendant Kaufman I understand it is agreed that he was the treasurer of the corporation, its general manager, and I don't know that there has been any agreement that he actually participated or shared in the responsibility of shipping the beer. Is that disputed?

MR. LEWIS: Yes, your Honor.

THE COURT: In view of the fact that it is disputed the burden is upon the Government to prove that Kaufman shared the responsibility of shipping this beer interstate. Even though it has appeared that the corporation actually shipped the beer, the corporation through its duly authorized agents, the burden is upon the Government to show that Kaufman himself individually participated in the shipment or he shared in the responsibility for the shipment, and when you decide this fact as to whether Kaufman shared in the responsibility of these shipments, you will take into consideration the fact—and I think it has been testified to here—that he owned all the stock in the



corporation, that he was treasurer and clerk and general manager, and then take into consideration the evidence with respect to his control of the affairs of the brewery that have been testified to here and described to you by the Government inspector Hannigan, who interviewed him at the brewery and furnished to him the different ingredients or pieces of evidence that have been introduced here. Take that all into consideration in deciding the fact as to whether or not Kaufman himself individually, as treasurer of the corporation or general manager of the corporation shared in the responsibility of these shipments interstate, Mr. Foreman and gentlemen. That fact is for you to decide.

*[Materiality of Quantity of Added Substance]*

Now we will proceed from the interstate aspect of this charge to the next essential element, that the Government charges—and I want you to have in mind that it must prove beyond a reasonable doubt—the Government charges and will have to prove to warrant a conviction of the defendants that fluorine in some form was added to the beer **by the corporation**, acting through its duly authorized agents, or by Kaufman, and I mean Kaufman through himself or his authorized agents or employees.

I want to point out to you that it is entirely unimportant and irrelevant how much the quantity of fluorine was which was added to the beer. The issue is, Was fluorine in some form added as an ingredient? If, as one of the Supreme Court cases says, it is an added deleterious ingredient, the statute denounces that. It is an added deleterious ingredient the statute denounces, not an added quantity of the deleterious ingredient.

Thus the gravamen or material charge in the section of the statute with which we are concerned is the addition of the deleterious substance and the quantity of the deleterious substance is of no moment. Hence, with respect to this element of the offence charged, if you find fluorine in any form was added,—and I say beyond a reasonable doubt,—then the Government has sustained its burden in that connection.

To emphasize the fact—and I want to make this plain—that the quantity of fluorine added to the beer has no relevancy here, I think I might point out to you that there is a section of the Food and Drug Act—I have already read it—where the quantity contained in a food may be of con-

siderable importance, and that is where it has been charged under Section 402 (a) (1) of the statute which deals with adulterated foods where the deleterious substance has not been added. That section reads as follows:

“A food shall be deemed to be adulterated (a) (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health.”

Quantity is of course important in determining whether or not it may be harmful, and quantity would be the test under this section, but not by any means under the section of the statute with which we are concerned here.

Congress recognized that nature's products such as grain, salt, hops, water, contained poisonous substances in small amounts and that they were not a danger or evil so long as the poisonous substance was not extracted by artificial process and added, and the users of these substances in their product are not punishable provided the quantity of such substances in the food does not ordinarily render it injurious to health.

To repeat, in this latter section that I have just read to you as to quantities, quantity is the test, but in the case of an added ingredient quantity is irrelevant and the only question involved where it is added is, was it added? Was it deleterious? Was it unsafe?

*[Material Question Involved]*

There are some other considerations and some other matters of importance in this case that I want to point out to you at this point so that you will have these issues clearly before you and so that you will have an intelligent and a knowing idea of just what you are to decide here.

It is of no importance under the section of the statute under which these defendants are being prosecuted that no evidence has been introduced to show someone drank this beer and was harmed. The question here is, not whether the beer was harmful—“deleterious” is the word in the statute, but whether the fluorine if it was added was harmful.

It is of no importance that an expert witness who took fluorine into his system said he was not harmed as far as he knew. In fact, though he said he felt no harmful effects, yet he still may have been harmed, according to the evidence. What did he say? As I remember the testimony—and



remember although I had a right to comment and give my opinion on the testimony, yet the testimony is for you in the last analysis—this witness said, as I remember, that he was not in a position to know whether he was harmed or not, but he felt no ill effects himself.

The Government does not have to show in this case how much beer would have to be drunk to harm a person.

It is of no importance in this case that tea or salt contain fluorine in quantities not harmful to health if ordinarily used.

It is of no importance that one bottle of this beer or five or fifty would or would not be harmful if drunk. The question to keep before you is whether fluorine itself is harmful and poisonous, and if so the statute says it cannot be added in any form to a food product without running afoul of the law.

*["Poisonous or Deleterious Substance"]*

Now, we pass on to the essential elements of the Government's charge. Is fluorine a poisonous or deleterious substance? You have heard the testimony of all the experts with respect to this particular issue as to whether or not fluorine is deleterious or harmful. You heard the testimony, I think it was of Professor Carlson, how he described it. I think he said that eight parts in a million were harmful, that it was harmful if it contained, or anything contained eight parts in a million. And then you heard the testimony of other experts with respect to whether or not this fluorine was a poisonous or deleterious substance.

These words in the statute, "poisonous and deleterious" have their plain, natural meaning, Mr. Foreman and gentlemen, and "poisonous" defined by Webster's New International Dictionary is, "Any agent which, introduced into an organism, may chemically produce an injurious or deadly effect". And "deleterious" is defined as "hurtful or destructive".

Take into consideration—I am not going to repeat it in detail—all the evidence you have heard here. Take into consideration the fact that fluorine would kill rats, take into consideration the testimony of the Professor, Dr. McNally, for the defendant, who said, I believe, that if he drank enough fluorine, assuming that it contained 15.2 parts per million, if he drank about 15 bottles of this beer he would be apprehensive at that point because he had given about that amount of fluorine to rats and killed rats with it.

Now, taking into consideration the plain meaning of the word "poison," that poison is any agent which, introduced in an organism, may chemically produce an injurious effect, and taking again into consideration, keeping in mind "deleterious", its plain meaning, natural meaning in the statute, that it means hurtful or destructive, on all the evidence you have heard here, answer the question in your own minds.

The Government must prove beyond a reasonable doubt, of course, that essential element of the offense and you decide that issue, is fluorine a poisonous, deleterious substance?

I cannot impress upon you too much but to point out to you again, to repeat, that the issue is whether this beer that these defendants put out, that the corporation put out, that Kaufman put out, and sent interstate is deleterious. The question is, is fluorine itself deleterious?

*[Fluorine Not Necessary in Production of Beer]*

The next element the Government must prove is that the fluorine was unsafe within the meaning of the statute, and what is unsafe has been defined, so I charge you that if the Government has proved beyond a reasonable doubt that the fluorine was not required and could be avoided by good manufacturing practice, you would be warranted in finding that the beer was unsafe, the food here or beer was unsafe within the meaning of the statute.

We have had with respect to that particular issue the testimony of the brewer from the Boston Brewing Company. There was no other evidence in the case on that point. He said categorically, as I remember, that fluorine was not necessary in the production of beer and it could be avoided by good manufacturing practice.

I have outlined all the essential elements charged, and if you can find that the Government has proved them all beyond a reasonable doubt you will find both the defendants guilty. On the other hand, if the Government has failed to prove any one of the essential elements of the charge, you will find the defendants not guilty.

*[Intent Is Not an Element]*

There is just one other matter and I am done. In many offences that we try here in the criminal court, intent, knowledge or conscious wrong-doing is an essential element of the offence. This is referred to generally and commonly as "criminal intent".



However, the Government does not have to establish any criminal intent here. Kaufman, if he shipped beer or shared in the responsibility or participated in the shipping of this beer interstate, did so at his own risk. The Government does not have to prove he knew it contained fluorine. If he shared in the responsibility of the shipments, the beer contained added fluorine and that fluorine was poisonous and deleterious and unsafe within the meaning of the statute, that is, it was adulterated, it would be of no consequence whether or not the beer was adulterated through his intention or negligence, or that he had knowledge of it or that he was acting in good faith. As Mr. Lewis pointed out here good faith is no defense, and as I said before, the defendants, if they shipped adulterated beer, they did so at their own risk.

There is just one other matter to point out to you. In a criminal case verdicts are rendered orally. When you return to this court room you will be asked to give me your verdict with respect to each separate count and you will be asked whether or not you find the defendants guilty or not guilty, with respect to Count One right through to Count Eight.

*[Government Need Not Show How Fluorine Was Added]*

I will see counsel now.

(After a conference with counsel, the court further charged the jury):

THE COURT: Just one additional thing, Mr. Foreman and gentlemen. You will take the case and retire to your jury room and decide it. It is not incumbent upon the Government to show specifically how the fluorine, if you find it was added, was put into the beer. There has been no testimony as I understand it, and the Government experts could not determine the exact form in which it was put into the beer, so that I charge you that it is not incumbent on them to show specifically how the added substance, if it was added, was added. The burden is on them to show it was added. There is no burden upon them to show how it came into the beer.

[The jury returned a verdict of guilty on all counts against both defendants, and on June 6, 1945, the court imposed fines of \$5,000 against each defendant, and further imposed a suspended sentence of 6 months in jail upon the individual defendant and placed him on probation for 3 years.]

---

**UNITED STATES v. ALBERTY, AN INDIVIDUAL TRADING UNDER THE FIRM NAME OF ALBERTY  
FOOD PRODUCTS**

United States District Court for the Southern District of California, Central Division. No. 18183-BH. May 20, 1946. 65 F. Supp. 945.  
Reversed, 159 F. 2d 278. See page 332.

In a criminal prosecution against the defendant for having shipped in interstate commerce a drug alleged to be misbranded, there had been a lapse of 71 days between the shipping of circulars pertaining to the drug and the drug itself. The circulars accompanied the drug so as to constitute labeling since both had been shipped in interstate commerce, had had a common destination, and had been displayed together.

Sections 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

When the drug and related circular came together, the prohibited act occurred, irrespective of the circuitous route each may have traveled.

Sections 201 (m), 301 (a), Federal Food, Drug, and Cosmetic Act.

The Act has with unanimity been liberally construed to protect the consuming public.

Title, Federal Food, Drug, and Cosmetic Act.

The courts have not applied the usual rule of strict construction of criminal statutes to the Act, but have given it a liberal construction to accomplish its remedial purposes.

Title, Federal Food, Drug, and Cosmetic Act.



The word "accompany" means that when a drug and related circular, having a common source and destination, come together at their destination, they become one in so far as the buying public is concerned, each, in effect, accompanying the other, whether they arrived at their common destination simultaneously or otherwise.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

Charles H. Carr, U. S. Attorney, and James M. Carter, Ernest A. Tolin, and Walter S. Binns, Assistant U. S. Attorneys, for the plaintiff.

Hauerken, Ames & St. Clair, San Francisco, Cal., and O'Conner & O'Conner, Los Angeles, Cal., for the defendant.

[*Nature of Proceeding*]

HARRISON, District Judge: This is a criminal case wherein the defendant is charged in twenty-three (23) counts with a violation of the Federal Food, Drug, and Cosmetic Act (Title 21, U. S. C. A., Sec. 301 *et seq.*). All counts, with the exception of Count XXIII, have been dismissed, and the case has been submitted to me on an agreed stipulation of facts, jury trial having been waived by both parties.

[*Pertinent Provision of Statute*]

All the allegations of Count XXIII are admitted, except that the defendant denies the offending circular accompanied the drug in interstate commerce within the definition of "labeling" under the provisions of 21 U. S. C. A., Sec. 321 (m):

"Sec. 321 (m)—The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

[*Facts*]

The stipulation of facts discloses that the leaflets were shipped on February 7, 1944, while the drugs were not shipped until April 25, 1944. Thus there was a lapse of seventy-one (71) days between the shipping of the offending circulars and the drug. Both were shipped in interstate commerce, had a common destination, and were displayed together.

[*The Issue Involved*]

Thus the sole issue is whether the drug and leaflets accompanied each other within the purview of the Act. Stating the issue differently, can the salutary objectives of the Act be circumvented by permitting a lapse of time to exist between the shipment of the drugs and offending leaflets from a common source to a common destination? I think not.

[*Cases in Point*]

I have been able to find but three cases that may be deemed as precedents. The first case is one from our own circuit, to-wit: *United States v. Research Laboratories, Inc.*, 126 F. (2d) 42, 45, wherein the Court stated:

"The libel does not state, nor is it material, whether the packages and circulars did or did not travel in the same crate, carton or other container, or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey."

The defendant feels that this case supports her position because of the simultaneous arrival of the offending articles. The facts in *United States v. Research Laboratories, Inc.*, *supra*, indicated a simultaneous arrival and that was as far as the Court was called upon to go. The Court's attitude towards a liberal interpretation of this Act is clearly brought out, when the Court further stated:

"The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A., Sec. 301 *et seq.*, is designed, to prevent injury to the public health. *A. O. Andersen & Co. v. United States*, 9 Cir., 284 Fed. 542, 543; *United States v. 48 Dozen Packages of Gauze*, 2 Cir., 94 Fed. 2d, 641, 642."

The second case that conforms to my conclusions is *United States v. Lee*, 131 F. (2d) 464. As in the case at bar, the circulars were shipped in interstate commerce separately from the products to which they relate. Therein the Court held as follows:

"The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with', 'to go with or attend



as a companion or associate', and 'to concur in association with,' Webster's New International Dictionary, 2d Ed. There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale."

The third case is *United States v. 7 Jugs etc.*, 53 Fed. Supp. 746, wherein an attempt was made to circumvent the Act by permitting a lapse of time to occur between the shipment of the related articles. The Court disposed of this issue in the following language:

"The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary 'misbranded' status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control."

[*Act Promulgated To Protect Public*]

Besides the foregoing formidable authorities, common sense and reason dictates the same conclusion. The Act was primarily promulgated to protect the consuming public. *United States v. Two Bags, etc.*, 147 F. (2d) 123-127. If that is true, what difference does it make in what manner the circular and drug made their interstate journey, so long as they eventually came together upon the merchant's shelf, there to mislead and defraud the consuming public? When the drug and related circular came together, the prohibited act occurred, irrespective of the circuitous route each may have traveled.

The Act involved has with unanimity been liberally construed to protect the consuming public from the avaricious. *U. S. v. 95 Barrels of Vinegar*, 265 U. S. 438, 44 S. Ct. 529, 68 L. Ed. 1094; *U. S. v. Antikamnia Chemical Co.*, 231 U. S. 654, 655, 34 S. Ct. 222, 58 L. Ed. 419; *U. S. v. Schider*, 246 U. S. 519, 522, 38 S. Ct. 369, 62 L. Ed. 863;

*A. O. Andersen and Co. v. U. S.*, 284 Fed. 542; *C. C. Co. v. U. S.*, 147 Fed. (2d) 820; *U. S. v. Commercial Creamery Co.*, 43 Fed. Supp. 714.

[*Defendant Relies Upon Strict Interpretation of Act*]

The defendant relies solely upon a strict interpretation of the statute invoking the principle set forth in the dissenting opinion of Mr. Justice Murphy in *United States v. Dotterweich*, 320 U. S. 277, and again in the recent opinion of the Supreme Court in *M. Krause & Bros. v. United States*, decided on March 25, 1946.

[*Act Given Liberal Construction*]

The cases heretofore cited clearly indicate that our courts have not applied the usual rule of strict construction of criminal statutes to this Act, but have given it a liberal construction and thus enabled the Act to accomplish its remedial purpose of protecting public health and pocket book against misbranded foods and drugs.

"Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. \* \* \* But that is not the way to read legislation. Literalism and evisceration are equally to be avoided." (Mr. Justice Frankfurter in *U. S. v. Dotterweich*, 320 U. S. 277.)

"All construction is the ascertainment of meaning. And literalness may strangle meaning." (Mr. Justice Frankfurter in *Utah Junk Co. v. Paul A. Porter, etc.*, U. S., decided April 22, 1946.)

If this Act is to be treated as a working instrument and not merely as a collection of English words, it must be interpreted as a living and vitalized Act. The defendant seeks, through literalism and evisceration, to avoid her studied attempt to circumvent the Act.

[*Conclusion*]

I hold that the word "accompany" as used in the Act means that when a drug and a related circular, having a common source and a common destination, come together at their destination, they are united and become one in so far as the buying public is concerned, each, in effect, accompanying the other, whether they arrived at their common destination simultaneously or otherwise.

In view of my conclusions herein expressed, it is my opinion the drug described in Count XXIII was misbranded contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, and therefore the defendant is guilty as charged.



## UNITED STATES v. DOUGLAS

United States Circuit Court of Appeals for the Seventh Circuit. No. 8970.

June 15, 1946. 155 F. 2d 894.

In the trial of a criminal action instituted for alleged violations of the Act, the trial judge sent to the jury the criminal information, to which were attached two affidavits of probable cause. Although the court had instructed the jury that the information was no evidence of the defendant's guilt, the submission of the affidavits to the jury was an infringement of the defendant's rights under the Sixth Amendment to the Constitution.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

George F. Callaghan, William H. Murphy, and Alfred Roy Hubert, all of Chicago, Ill., for appellant.

J. Albert Woll, U. S. Atty., and Robert C. Eardley, Asst. U. S. Atty., both of Chicago, Ill., Theron L. Caudle, Asst. Atty. Gen. (Vincent A. Kleinfeld, Attorney, Department of Justice, Arthur A. Dickerman and William W. Goodrich, Attorneys, Federal Security Agency, all of Washington, D.C., of counsel), for appellee.

Before SPARKS, MAJOR and KERNER, Circuit Judges.

[*Nature of Proceeding*]

MAJOR, Circuit Judge: This is an appeal from a judgment of conviction predicated upon an information filed by the United States District Attorney, which charged a violation of numerous sections of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301, *et seq.*

[*Ground for Reversal*]

Defendant urges numerous grounds for reversal, but inasmuch as we are of the view that the judgment must be reversed on one of such grounds, it is unnecessary to state or discuss the others. The court sent to the jury the information, to which were attached two affidavits, each of which contained convincing proof in support of the charges contained in the information. One of the affidavits was made by a person called as a witness at the trial, the other was not. We see no reason to set forth the contents of these affidavits. It is sufficient to state that they strongly supported the government's case; in fact they contained proof of every element essential to a conviction.

[*Question at Issue*]

The question therefore is, was the submission of these affidavits to the jury reversible error? The government attempts to excuse their submission almost entirely by the fact that the court instructed the jury in the usual form to the effect that the information was no evidence of the defendant's guilt, that it was not to be treated by the jury as raising any kind of presumption against the defendant, and that it was sim-

ply the formal manner prescribed by law for preferring a charge and should be regarded by the jury solely in that light. A number of cases are cited in which this general instruction has been approved. We need not cite or discuss them for the reason that they are beside the point. No complaint is made because the information was permitted to go to the jury, but the criticism is directed solely at the affidavits. It is one thing to send to the jury an indictment or information, the accusation against the defendant, but something entirely different to send affidavits containing the government's proof in support of such accusation. We know of no authority and we suspect there is none which condones, much less approves, such a procedure.

[*Government's Argument*]

It is pointed out by the government that these affidavits were required by the court as a prerequisite to its granting leave to file the information. This no doubt was a proper procedure. The filing of an information is discretionary with the court and leave must be obtained. In the exercise of this discretion, it may properly require that in some manner it be satisfied of probable cause for a prosecution. One of the ways by which it may be so satisfied is by the filing of affidavits. See *Albrecht v. United States*, 273 U. S. 1, 5.

It is also suggested that the affidavits were attached to the information and became a part thereof. We are unable to discern how this affects the situation. We know of no reason why they should be attached to the information other than per-



haps for the purpose of convenience. In any event, they are no part of the charge, and their sole function is to serve as proof in convincing the court that leave should be granted to file. Furthermore, the fact that they were attached to the information furnishes no reason why they could or should not have been detached before the information was sent to the jury.

The government is in a dilemma in attempting to sustain its position. In one breath it concedes, as it must, that these affidavits were submitted to the court as proof in support of the charge for the purpose of inducing the court to grant leave to file, and in the next breath argues that when these same affidavits were submitted to the jury they were merely a part of the accusation and constituted no proof in support thereof. This latter argument is untenable and must be rejected. In fact, we think that there would be no difference in effect or result if the transcript of the testimony given before a grand jury as the basis for an indictment was submitted to the trial jury. Surely no one would seriously contend but that such procedure would constitute prejudicial error.

*[Question Not Raised in Lower Court]*

Lastly, the government urges that this court ignore the error for the reason that it was neither excepted to nor assigned as error by the defendant. Again the government is in a rather awkward situation. There is nothing in the record, including the court's charge to the jury, to show or indi-

cate that either defendant or the court had any knowledge that these affidavits were being submitted to the jury. The court instructed the jury concerning the information and of course all had knowledge that it was being submitted. Obviously, defendant's counsel could not be expected to object to the submission of the affidavits unless he had knowledge thereof. True, as pointed out, the court no doubt had knowledge that the affidavits were attached to the information at the time leave was granted to file, but it does not follow that it had such knowledge at the time it submitted the information. Furthermore, it may be that the court presumed that counsel for the government would make it his business, as he should have done, to ascertain that these affidavits were detached. Counsel for the government was the moving factor in the matter and must be held responsible for a procedure which, in our judgment, was unfair, prejudicial and attended with dangerous consequences.

*[Question Too Serious To Go Unnoticed]*

Furthermore, we are of the view that the question presented is too serious to go unnoticed even though it was not properly raised in the court below. Amendment VI of the Constitution of the United States provides: "In all criminal prosecutions, the accused shall enjoy the right \* \* \* to be confronted with the witnesses against him." The submission to the jury of the affidavits complained of was a palpable infringement of this constitutional right.

The judgment is REVERSED.

---

**UNITED STATES v. SULLIVAN, AN INDIVIDUAL,  
TRADING AS SULLIVAN'S PHARMACY**

United States District Court for the Middle District of Georgia, Columbus  
Division. Information No. 3688. June 19, 1946. 67 F. Supp. 192.

Reversed, 161 F. 2d 629. See page 334.

Circuit Court of Appeals reversed, 332 U. S. 689. See page 350.

A retail druggist was prosecuted for violating Section 301 (k) of the Act. The druggist, in Georgia, had purchased from a wholesaler in that state a bottle containing 1000 sulfathiazole tablets which had theretofore been transported in interstate commerce. The 1000-tablet bottle, pursuant to regulation of the Federal Security Administrator, bore the legend that the product was to be used only by or on the prescription of a physician, and warnings. The druggist removed 12 tablets from the bottle, placed them in a small box containing only the word "sulfathiazole," and sold them to a purchaser without a prescription. A motion to dismiss the information was denied.

Sections 201 (g), 301 (k), Federal Food, Drug, and Cosmetic Act.



The Federal Food, Drug, and Cosmetic Act has been held to be a lawful exercise by Congress of its power under the Commerce Clause of the Constitution.

Sections 201 (b), 301 (k), 901, Federal Food, Drug, and Cosmetic Act.

Congressional authority under the Commerce Clause includes the power to regulate intrastate activities which "affect" interstate commerce or which are in the "flow" of interstate commerce.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act, to prevent the misuse of the facilities of interstate commerce in placing before the consumer misbranded and adulterated articles, could not be accomplished if Section 301 (k) had been omitted.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

Federal authority extends far enough to control the labels on goods being offered for sale to consumers after shipment in interstate commerce.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

By Section 301 (k), Congress has sought not only to protect and foster interstate commerce, but also to prevent the impairment of the effect of other provisions of the Act. This it may lawfully do.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

By Section 301 (k), Congress has sought to prevent individuals from interfering with the labeling of articles that have been shipped in interstate commerce.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

By Section 301 (k), Congress has exhibited the character of the means it deemed necessary to carry out the purpose of the statute, and has kept within Constitutional bounds.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

It is apparent that Congress, in Section 301 (k), intended to preserve the integrity of the labeling of an article that had been shipped in interstate commerce until it reached the consumer, even though the article might no longer be in interstate commerce.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The acts of the defendant complained of were in fact alteration or obliteration of the label, as well as the doing of the acts other than those enumerated in Section 301 (k), with respect to the drug.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The design of Congress to extend the protection of the consumer contemplated by the law to the full extent constitutionally possible is clearly expressed in the legislative history of Section 301 (k). The language of the section coupled with the legislative history, read in the light of the purposes of the statute, affords no room for doubt that the acts of the defendant complained of were within the meaning and purpose of the statute.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

It was immaterial that the defendant had obtained his supply from a distributor within the state wherein defendant had his place of business.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

In construing Section 301 (k), the court should be guided by the purposes of the Act and the intention of Congress therein evidenced, and should seek to make that intention effectual. The court should look to the policy of the legislation as a whole, the reason for its enactment and its antecedent history, and give it an effect in accordance with its design and purpose. Regard should also be had to the evils which called forth the statute, and a construction should be adopted which serves to correct the evil and defeat the wrong it was its purpose to frustrate.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.



The Act is a remedial one, intended to protect the public health and pocketbook, and should be liberally construed.

Title, Federal Food, Drug, and Cosmetic Act.

John P. Cowart, U. S. Attorney, and Jack J. Gautier, Asst. U. S. Attorney, both of Macon, Ga., for the U. S.

Hatcher & Hatcher (J. Madden Hatcher, of counsel), Columbus, Ga., for defendant.

[*Nature of Proceeding*]

DAVIS, District Judge: This is a criminal prosecution by information in two counts,<sup>1</sup>

charging violations of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 301 *et seq.*). It is alleged in each count, in

<sup>1</sup> Count I (charging part):

"That the Abbott Laboratories, trading and doing business at North Chicago, State of Illinois, did, within the period from on or about November 25, 1943 to on or about March 15, 1944, ship in interstate commerce from North Chicago, State of Illinois, to Atlanta, State of Georgia, consigned to the Abbott Laboratories, a number of boxes, containing a number of bottles, each bottle containing a number of tablets of a drug within the meaning of the Act of Congress of June 25, 1938, known as the Federal Food, Drug, and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C. 321 (g) (2));

"That one of said bottles containing said drug when shipped in interstate commerce, as aforesaid, was labeled, marked and branded by means of a label affixed thereto bearing the following printed and graphic matter, to-wit:

1000 Tablets (Bisected)

SULFATHIAZOLE

(2-sulfanilamidothiazole) 0.5 gm. (7.7 grs.)

Abbott—List No. 3430

Caution—To be used only by or on the prescription of a physician.

Warning: In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

F5 Serial No. 311T237

Abbott Laboratories

North Chicago, Ill., U. S. A.

"That thereafter, to-wit, on or about September 29, 1944, the said Abbott Laboratories at Atlanta, Georgia, did sell and deliver said bottle of said drug in the identical condition as when shipped in interstate commerce, as aforesaid, and labeled, marked and branded, as aforesaid to Jordan James Sullivan, an individual, operating under the name Lynwood Pharmacy, Columbus, Georgia, and the said Jordan James Sullivan transferred said bottle of drug and caused said bottle of drug to be transferred to Sullivan's Pharmacy, Columbus, Georgia, a pharmacy owned and operated by said Jordan James Sullivan;

"That on or about December 13, 1944, while a number of said tablets of said drug contained in said labeled bottle, as aforesaid, were being held for sale after shipment in interstate commerce, as aforesaid, at said Sullivan's Pharmacy, the said Jordan James Sullivan did, at Columbus, Georgia, within the Columbus Division of the Middle Judicial District of Georgia

and within the jurisdiction of this Court, then and there cause to be removed a quantity of said tablets of drug, to-wit, 12 tablets of said drug from said bottle labeled as aforesaid and sold and delivered, as aforesaid, and being held for sale as aforesaid, and did cause to be repacked said 12 tablets of said drug so removed into a box and did cause to be sold and disposed of the said box containing the said 12 tablets to one Joe P. Durham, solely upon the surrender by the said Joe P. Durham of money in payment therefor;

"That said box into which said 12 tablets were repacked was labeled, marked and branded with the following written and graphic matter, and no other, to-wit:

SULFOTHIAZAL

"That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said 12 tablets of drug being misbranded within the meaning of said Act of Congress (21 U. S. C. 352 (f) (1)), in that the labeling of said drug in said box failed to bear adequate directions for use, to wit, in that the said box containing said 12 tablets of drug, bore no labeling containing directions for use;

"That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said drug in said box aforesaid being further misbranded within the meaning of said Act of Congress (21 U. S. C. 352 (f) (2)), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users, in that the said box containing said tablets of drug bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration;

"That said act by said Jordan James Sullivan, the defendant herein, of causing the removal from said labeled bottle, repacking into said box labeled as aforesaid and disposing of said 12 tablets of said drug, as aforesaid, was an act done by said Jordan James Sullivan while said article of drug was being held for sale after shipment in interstate commerce, as aforesaid, which resulted in said 12 tablets of drug being misbranded, as aforesaid, in violation of said Act of Congress (21 U. S. C. 331 (k))."

Count II similar to Count I, except as to name of purchaser and relating to "Sulfathiazole" rather than "Sulfothiazal".



substance, that a drug manufacturer in North Chicago, Illinois, shipped in interstate commerce to its distributor in Atlanta, Georgia, a bottle containing 1000 Sulfathiazole tablets; that the distributor thereafter sold and delivered said bottle of tablets to the defendant, the owner of drug stores in Columbus, Georgia; that while the tablets in said bottle were being held for sale at one of the defendant's drug stores, after shipment in interstate commerce, the defendant caused 12 tablets to be removed from the bottle and placed into a box and disposed of by sale; that the box into which the tablets were placed and which was sold bore only the label "Sulfothiazal," as described in Count One and "Sulfathiazole," as described in Count Two; that the act of removing, repacking, and disposal resulted in the drug being misbranded in two different respects under the Federal Food, Drug, and Cosmetic Act.

[*Pertinent Provision of Act*]

It is charged that these acts constitute violations of Section 301 (k) of the Act, (21 U. S. C. 331 (k)). The pertinent provision of this section of the Act is as follows:

"Section 301, 21 U. S. C. 331: The following acts and the causing thereof are hereby prohibited: \* \* \* (k) The adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a, \* \* \* drug \* \* \*, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

[*Defendant's Motion To Dismiss*]

The defendant filed a Motion to Dismiss setting forth four grounds: (1) the allegations of the information are insufficient as a matter of law to constitute any offense against the laws of the United States; (2) the alleged acts of the defendant were not in interstate commerce and were beyond the power of Congress to regulate, control, or punish; (3) the applicable provisions of the law only apply to misbranding in interstate commerce; (4) that if section 301 (k) of the Act is construed as applying to the alleged acts of the defendant, said section is unconstitutional as being beyond the legislative power of Congress and an invasion of the reserved police powers of the states.

[*Matters Considered*]

We will consider in this opinion:

(1) Whether Section 301 (k) of the Act is a lawful exercise by Congress of its

powers under the commerce clause of the Constitution; and

(2) Whether the acts of the defendant alleged in the information are cognizable under this section of the Act.

[*Federal Food, Drug, and Cosmetic Act Is Constitutional*]

The Federal Food, Drug, and Cosmetic Act (passed in 1938) and its predecessor, the Food and Drug Act of 1906, have been held to be lawful exercises by Congress of its power under the commerce clause of the Constitution. In *Hipolite Egg Co. v. United States*, 220 U. S. 45 (1911), in speaking of the 1906 Act, the court said at p. 57:

"The statute rests, of course, upon the power of Congress to regulate interstate commerce, and, defining that power, we have said that no trade can be carried on between the States to which it does not extend, and have further said that it is complete in itself, subject to no limitations except those found in the Constitution."

In *United States v. Dotterweich*, 320 U. S. 277 (1943), a case under the 1938 Act, the court said at p. 280:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience."

[*Authority of Congress Under Commerce Clause*]

It is well settled that congressional authority under the commerce clause includes the power to regulate interstate activities which "affect" interstate commerce or which are in the "flow" of interstate commerce. It was said in *Oklahoma v. Atkinson*, 312 U. S. 508, 526 (1941):

"As repeatedly recognized by this Court from *McCulloch v. Maryland*, 4 Wheat. 316, to *United States v. Darby*, 312 U. S. 100, the exercise of the granted power of Congress to regulate interstate commerce may be aided by appropriate and needful control of activities and agencies which, though intrastate, affect that commerce."

In *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 36-37 (1937), the court declared:

"The congressional authority to protect interstate commerce from burdens and obstructions is not limited to transactions which can be deemed to be an essential part of a 'flow' of interstate or foreign



commerce. Burdens and obstructions may be due to injurious action springing from other sources. The fundamental principle is that the power to regulate commerce is the power to enact all appropriate legislation 'for its protection or advancement' \* \* \* ; to adopt measures 'to promote its growth and insure its safety' \* \* \* ; 'to foster, protect, control and restrain'. \* \* \* That power is plenary and may be exerted to protect interstate commerce 'no matter what the source of the dangers which threaten it.'"

[*Intrastate Activities Subject to Federal Control*]

The following recent cases have determined some phases of intrastate activities that are properly subject to federal control. *Curran v. Wallace*, 306 U. S. 1 (1939); *Mulford v. Smith*, 307 U. S. 38 (1939); *United States v. Rock Royal Co-operative Inc.*, 307 U. S. 533 (1939); *United States v. Darby*, 312 U. S. 100 (1941); *United States v. Wrightwood Dairy Co.*, 315 U. S. 110 (1942).

The authority of Congress over goods which have moved in interstate has operated to prevent numerous acts to those goods: e. g., the imposition of discriminatory taxes, *Sonneborn v. Cureton*, 262 U. S. 506 (1923); the requirement of label removal, *McDermott v. Wisconsin*, 228 U. S. 115 (1913); the receiving etc. of stolen motor vehicles, *Brooks v. United States*, 267 U. S. 432 (1925); the placing of restrictions on an importer in selling an article in convenient containers, *Baldwin v. Seelig*, 294 U. S. 511 (1935).

[*Purpose of Section 301 (k)*]

That Congress in enacting Section 301 (k) of the Act intended to exercise its broad powers under the commerce clause is clearly expressed in the legislative history of the Act. In H. R. Rep. No. 2139, 75th Cong., (3rd Sess., 1938), submitted by the Committee on Interstate and Foreign Commerce to accompany S. 5, the bill which was enacted as the present Act, it was stated in speaking of Section 301:

"In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."

One of the purposes of the Federal Food, Drug, and Cosmetic Act is to "prevent the misuse of the facilities of interstate commerce in conveying to and placing before

the consumer misbranded and adulterated articles of medicine or food". *McDermott v. Wisconsin*, 228 U. S. 115, 133 (1913); *United States v. Two Bags . . . Poppy Seeds*, 147 F. (2d) 123, 127 (C. C. A. 6th, 1945). This purpose could not have been accomplished if the provision now being considered had been omitted. Its absence would have made it relatively simple, in many instances, to render nugatory the misbranding provisions of the Act by simply shipping in interstate commerce properly labeled articles and misbranding them after the transportation had ended. Anticipating resort to such stratagem, whether as part of a scheme or not, Congress sought to prevent it by the enactment of subsection (k) which would preserve the integrity of labeling of an article that had been shipped in interstate commerce until it reached the consumer. "Any rule, \* \* \* which is intended \* \* \* to prevent the flow of commerce from working harm to the people of the nation, is within the competence of Congress." *Mulford v. Smith, supra*, 307 U.S. 38.

[*McDermott Case*]

That federal authority extends far enough to control the labels on goods being offered for sale to consumers after shipment in interstate commerce was decided in *McDermott v. Wisconsin, supra*. In that case a Wisconsin statute required that certain syrups bear labels prescribed in the statute and none other. McDermott, a retail merchant in Wisconsin, received from Chicago a box containing 12 cans of syrup, which he placed on the shelves of his establishment for retail sale. The label of the syrup, when received by McDermott, complied with the Federal Food and Drugs Act of 1906, but did not comply with the state law. In order to meet the state law requirements, the labels of the cans would have had to be removed and new ones substituted. In holding that the state could not require the removal of the label that met the requirements of the federal law, the court said at p. 133 in speaking of the state law:

"\* \* \* to permit such regulation as is embodied in this statute is to permit a State to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statutes which have accrued both to the Government and the shipper, and to impair the effect of a Federal law which has been enacted under the Constitutional power of Congress over the subject."



## [Power of Congress Over Commerce]

By section 301 (k) Congress has sought, not only to protect and foster interstate commerce, but also to prevent the impairment of the effect of other provisions of the Act. This it may lawfully do. "It is the law that when Congress properly enters the field of its authorized activity, it may not only adopt means necessary, but, in a like manner, means convenient to the exercise of its power". *Board of Trade v. Milligan*, 16 F. Supp. 859, 861 (W. D. Mo. 1936); aff'd 90 F. (2d) 855; cert. den. 302 U. S. 710 (1937).

In the *McDermott* case, the article that had been shipped in interstate commerce was subject to federal authority to the extent of prohibiting a state from interfering with its label. Such interference by the state impinged upon one of the lawful means that Congress had selected for the protection of the consumer. By section 301 (k) Congress seeks to prevent individuals from interfering with labeling of articles that have been shipped in interstate commerce. Since federal authority can require the preservation of labels on articles that have been shipped in interstate commerce, notwithstanding attempted state regulation, it is a corollary that federal authority may require individuals to preserve such labels and punish acts that result in such articles being misbranded.

## [Schechter Case]

In *A. L. A. Schechter Poultry Corp. v. United States*, 295 U. S. 495 (1935), cited and strongly relied on by the defendant, the Court drew the distinction between intrastate activities that directly affect interstate commerce and those that affect it indirectly. The court pointed out (p. 546) that the precise line, in determining how far the federal government may go, "can be drawn only as individual cases arise." The facts in the *Schechter* case, in which attempted regulations of intrastate activities were held to be beyond federal power, are clearly distinguishable from those in the instant case. There a "Live Poultry Code," which had been promulgated under the National Industrial Recovery Act, attempted to regulate almost every phase of the intrastate activities of the poultry business. These included hours, wages, labor conditions, number of employees, trade practices, etc. The regulations were general in nature and related to the conduct of the business, whether or not the commodity dealt with had been transported in interstate com-

merce. In holding that the regulations were invalid the court recognized (p. 544) that it is the "effect upon interstate commerce" not "the source of the injury" which is the criterion of federal power. In the statute here assailed the very article on which the act was done which resulted in its misbranding must have moved in interstate commerce. To hold that Congress has no power to prohibit such wrongful acts would permit the use of the facilities of interstate commerce to place before the consumer misbranded goods. "The power to regulate interstate commerce includes the power to prohibit its use to facilitate wrongful and injurious acts and practices." *Bailey v. United States*, 74 F. (2d) 451 (C. C. A. 10, 1934).

[Dissenting Opinion in *Hammer v. Dagenhart*]

An important Supreme Court pronouncement with respect to the Food and Drugs Act of 1906 appears in the dissenting opinion of Justice Holmes in *Hammer v. Dagenhart*, 247 U. S. 251 (1918). The majority opinion was recently expressly overruled by a unanimous Court in *United States v. Darby, supra*, where on page 115, the Court referred to "the powerful and now classic dissent of Mr. Justice Holmes." In his dissent in the *Dagenhart* case, Justice Holmes stated on page 279:

"The Pure Food and Drug Act which was sustained in *Hipolite Egg Co. v. United States*, 220 U. S. 45, with the intimation that 'no trade can be carried on between the States to which it (power of Congress to regulate commerce) does not extend', applies not merely to articles that the changing opinions of the time condemn as intrinsically harmful but to others innocent in themselves, simply on the ground that the order for them was induced by a preliminary fraud. *Weeks v. United States*, 245 U. S. 618. It does not matter whether the supposed evil precedes or follows the transportation. It is enough that in the opinion of Congress the transportation encourages the evil."

Here Justice Holmes gave recognition to the proposition that in the Food and Drugs Act of 1906 Congress did not confine its regulation of interstate commerce in such merchandise to the period of transportation alone, but properly struck at evils intimately associated with such commerce, though they might arise prior or subsequent to the transportation.

## [Purpose of Congress]

By the statute here in question Congress has in effect declared that if the facilities of



interstate commerce are used for the shipment of goods, no person may thereafter, while the goods are being held for sale, do any act with respect to the goods which misbrands them. The mischief, which the statute seeks to prevent, has a direct effect on interstate commerce. To hold that Congress may not prevent such acts would permit the facilities of interstate commerce to be used to the detriment of the public.

[*Two Other Cases Dealing with  
Section 301 (k)*]

So far as the Court is aware, there are only two reported cases that deal with the interpretation of this provision of the law. One of these cases is *United States v. Lee*, 131 F. (2d) 464 (C. C. A. 7, 1942), an injunction proceeding under section 302 of the Act (21 U. S. C. 332) to restrain, among other things, violations of section 301 (k). The defendant there caused circulars to be printed in which false claims were made for his drug products and after the goods were shipped in interstate commerce the drugs and circulars were displayed together which resulted in the goods being misbranded. The Circuit Court, in holding that this was a violation of section 301 (k) which could be restrained, said (p. 466):

"It (the Federal Food, Drug, and Cosmetic Act) was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale."

The other case which deals with this provision of the law is *United States v. 7 Jugs Dr. Salsbury's Rakos*, 53 F. Supp. 746 (D. Minn. 1944), a seizure under the Act. The court there commented as follows (p. 756):

"This Court does not in this proceeding propose to mark out the limits of Section 301 (k). Seemingly, however, it was enacted by Congress under its authority to regulate activities affecting interstate commerce. See *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1. In referring to alteration, mutilation, destruction, obliteration, or removal of labels, this section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded."

By the Federal Food, Drug, and Cosmetic Act, Congress has sought to prevent the use of facilities of interstate commerce in con-

veying to and placing before consumers adulterated and misbranded articles. That it may lawfully do this, the Court believes, is no longer open to question. Keeping within Constitutional limitation of authority Congress may determine for itself the means necessary to make its purpose effective. By section 301 (k) Congress had exhibited the character of the means it deemed necessary to carry out its purpose, and the Court thinks it has kept within Constitutional bounds.

[*Article Need Not Be in Interstate Commerce  
When Misbranded*]

The plan of section 301 of the Act clearly demonstrates the purpose of Congress. Subsection (a) prohibits the introduction into interstate commerce of an article that is misbranded at the time introduction takes place; subsection (b) prohibits the misbranding of an article in interstate commerce; subsection (k) prohibits the doing of any act with respect to an article after shipment in interstate commerce and while held for sale, that results in the article being misbranded.

It is unnecessary in considering this case to determine whether or not the articles on which the alleged acts were done were in interstate commerce at the time the misbranding took place. It might well be that in the instant case the article while on the shelf of the retailer was in interstate commerce. If this were so, the acts done might be acts of misbranding in interstate commerce, and a violation of Section 301 (b). The situation set forth in subsection (k) "while such article is held for sale after shipment in interstate commerce," does not preclude the possibility that the article at the same time may be in interstate commerce. But, under section 301 (k) it is sufficient to show interstate shipment of the article and the doing of the prohibited act while the article was held for sale. It is apparent that Congress intended to preserve the integrity of the labeling of an article that had been shipped in interstate commerce until it reached the consumer, even though the article was no longer in interstate commerce.

[*Charges in Information*]

The information charges that the act of the defendant, in causing the removal, re-packing, and disposal of the tablets, resulted in the drug being misbranded within the meaning of 21 U. S. C. 352 (f) (1) and (2). These provisions are as follows:



"A drug or device shall be deemed to be misbranded—(f) Unless its labeling bears (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."

It will be observed from the allegations of the information that the bottle containing the tablets, which was shipped in interstate commerce, did not bear adequate directions for use but bore the so-called "prescription legend." The regulation promulgated under the proviso of 21 U. S. C. 352 (f) exempted this article from bearing adequate directions for use. This regulation in effect at the time of the alleged violation,<sup>2</sup> 21 C. F. R. Cum. Sup. Sec. 2.106 (b) provided, among other things that a shipment of a drug shall be exempt from bearing adequate directions for use if it is made for use exclusively by or on prescriptions of physicians and bears the "prescription legend." The exemption is to remain effective until the drug is dispensed upon and under labels bearing the directions for use specified in prescriptions of physicians. This regulation as it affects the present case would require the drug to be sold on a physician's prescription and to bear the directions for use specified in the prescription. The "prescription legend" is not a substitute for adequate directions for use.

*[Tablets Labeled Legally When in Interstate Commerce]*

The bottle containing the tablets of drug when shipped in interstate commerce, traveling under the exemption, was labeled to comply with the law. It is charged that the act of the defendant in causing the removal, repacking and disposal of the tablets of drug in a container bearing only the written matter "Sulfothiazal" or "Sulfathiazole" resulted in its misbranding.

*[Contention of Defendant]*

It was strongly contended here by the defendant that the acts which are alleged to

constitute the violation were not one of those particularly enumerated in the statute, viz: "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling." This argument is untenable for two reasons. First, such acts are in fact alteration or obliteration of part of the label, and second, such acts, if not one of those enumerated, is the doing of some other act, other than those enumerated, with respect to the drug.

The bottle label which was proper bore considerable printed matter, including the name of the drug "Sulfathiazole" and the "prescription-legend," and required warnings. Clearly, if part of the label had been obliterated, leaving only "Sulfathiazal," misbranding would have resulted. Likewise, if the article is repacked into a container which bears only the printed matter "Sulfathiazal," there is equally a violation as being a combination of obliteration and alteration of the label.

Apart from this, the language of the statute "or the doing of any other act with respect to a \* \* \* drug," includes any other act other than those enumerated in the opening clause of sub-section (k). No restriction is made as to the character of the act prohibited, except that it must be "with respect to" the drug. Had it been the intention of Congress to prohibit acts upon the article itself, or to the original container, it would have been sufficient to proscribe any other act to the article. Instead, however, the more inclusive term "with respect to" was used. Not only are acts done to the article itself prohibited, but all acts falling within the larger category are prohibited by the statutory language. In *United States v. Lee, supra*, the court held that displaying circulars which contained false and misleading statements together with drugs that had been shipped in interstate commerce and resulted in the drugs being misbranded was cognizable under this section of the act.

The design of Congress "to extend the protection of consumers contemplated by the law to the full extent constitutionally possible" is clearly expressed in the legislative history. Congress in section 301 (k) did not use any language that would indicate that "held for sale after shipment in interstate commerce" referred to the original consignee, or while the article was in original unbroken packages, unloaded, or

<sup>2</sup> A new regulation with somewhat modified provisions concerning exemptions under this section became effective on October 10, 1945.



unsold. Congress used the broad language "while \* \* \* held for sale." In order to give effect to the purposes of the Act, the protection of the consumer, the prohibitions relating to the article must go along with it while it is being held for sale by anybody, whether the original interstate consignee, wholesaler, distributor, or retailer. The article in the hands of any dealer and until it reaches the ultimate consumer is being held for sale. This thought as it applied to producers was expressed by the Court in *Hipolite Egg Co. v. United States*, *supra*, where it was said:

"All articles, compound or single, not intended for consumption by the producer, are designed for sale, and, because they are, it is the concern of the law to have them pure."

[*Defendant Holding Article for Sale*]

Obviously, the defendant in this case, a retail druggist, who is charged with doing the prohibited acts, from the time he received the article until it was disposed of was holding it for sale. The buying of drugs and holding them for sale was part of his business. The language of the statute coupled with the statement from the legislative history, read in the light of the purposes of the Act, affords, in this court's opinion, no room for doubt that the acts charged are within the meaning and purpose of the statute.

[*Section 301 (k) Covers Products Purchased from Local Wholesalers*]

The defendant in this case, as retail druggists generally do, obtained his supply from a distributor within the state. If section 301 (k) is limited to a situation where the drugs which are being held for retail sale were received directly from outside the state, the protection of the public will be extensively curtailed. If retailers find that they can evade federal jurisdiction by purchasing drugs through local wholesalers, after receipt by the latter in the channels of interstate commerce, this provision of the act is nullified and the statute rendered partly ineffective. A statute should not be construed as to render it partly ineffective or inefficient or to cause public injury or inconvenience, if it can be construed in a way that will make it effective. *United States v. Powers*, 307 U. S. 214 (1939); *Bird v. United States*, 187 U. S. 118 (1902); *Sunshine Anthracite Coal Co. v. Adkins*, 310 U. S. 381 (1940).

The Supreme Court in *United States v.*

*Antikamnia Chemical Co.*, 231 U. S. 654, 667 (1914) said of the Food and Drugs Act of 1906:

"The purpose of the law is the ever insistent consideration in its interpretation."

And in *United States v. Dotterweich*, *supra*, the Court said of the present Act:

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation, if it is to be treated as a working instrument of government and not merely as a collection of English words."

[*Court Must Look to Policy of Legislation*]

In construing section 301 (k) the Court should be guided by the purposes of the Act, the intention of Congress therein evidenced, and seek to make that intention effectual. *United States v. Stone & Downer Co.*, 274 U. S. 225 (1927); *Rogers v. Peck*, 199 U. S. 425 (1905). The Court should look to the policy of the legislation as a whole, the reason for its enactment and its antecedent history and give it an effect in accordance with its design and purpose, so that its purpose may not fail. *Ozawa v. United States*, 260 U. S. 178 (1922); *United States v. American Trucking Ass'ns*, 310 U. S. 534 (1940). Regard should also be had to the evils which called forth the statute (*Fasulo v. United States*, 272 U. S. 620 (1926)), and a construction should be adopted which serves to correct the evil and defeat the wrong it was its purpose to frustrate. *Bernier v. Bernier*, 147 U. S. 242 (1832); *Rhodes v. Iowa*, 170 U. S. 412 (1898).

The Federal Food, Drug, and Cosmetic Act is a remedial statute, intended to protect the public health and pocket book, and should be liberally construed. *United States v. Dotterweich*, *supra*; *United States v. Two Bags . . . Poppy Seeds*, *supra*; *United States v. 7 Jugs . . . Dr. Salsbury's Rakos*, *supra*; *United States v. Research Laboratories*, 126 F. (2d) 42 (C. C. A. 9, 1945); *United States v. Commercial Creamery Co.*, 43 F. Supp, 714, (E. D. Wash. 1942).

[*Defendant Violated Act*]

So construing section 301 (k) of the Act there can be no doubt that the acts of the defendant alleged in the information constitute violations of those provisions of the law.

The defendant's motion to dismiss will be denied.



## UNITED STATES v. KORDEL

United States District Court for the Northern District of Illinois, Eastern Division. 45 CR 488. June 26, 1946. 66 F. Supp. 538.

Affirmed, 164 F. 2d 913. See page 343.

Affirmed, 335 U. S. 345. See page 382.

The defendant was prosecuted for having distributed drugs alleged to be misbranded because of false therapeutic claims contained in literature shipped apart from the drugs. It was held that the literature had been shipped by the defendant, that the drugs and literature had been sent to the same consignee, that the literature was displayed and had been intended to be distributed in relation to the drug, and that the literature, therefore, constituted accompanying labeling under the Act.

Sections 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Since the Act constitutes remedial legislation, the rule of liberal construction is to be followed irrespective of its penal provisions.

Title, Federal Food, Drug, and Cosmetic Act.

To adhere to the defendant's position that the definition of "labeling" should be construed differently in criminal cases than in condemnation actions would result in a strange situation wherein under the same statute, and the same section, a single word would have a different meaning dependent only on the nature of the action brought.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

J. Albert Woll, U. S. Attorney, for plaintiff.

James W. Breen, Chicago, Ill., for defendants.

#### Memorandum

LA BUY, District Judge: There are three informations, comprising twenty counts, brought against Laura Kordel and Lelord Kordel for violation of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 301 *et seq.*) by misbranding. A stipulation between Lelord Kordel tradings as Gotu Kola Distributors and as Lelord Kordel Products, and as Lelord Kordel Products and Nutrition Enterprises, has been filed wherein the facts contained in the three informations are agreed. This stipulation is not made by Laura Kordel and is not to be construed as admissions by her.

#### [Issue Presented]

With the stipulation of facts as stated in the informations, the only question tried by the court was whether the violation has been proved by the evidence.

#### [Contention of Defendant]

The main contention of defendants' counsel is that since the booklets did not, in a number of counts, physically accompany the drugs they did not therefore "accompany" the drug within the meaning of Sec. 201 (m) of the Act. Defendants' counsel urges a strict construction of the word "accompany" since this is a criminal action and

that the penal provisions of the Federal Food, Drug, and Cosmetic Act be strictly construed.

#### [Purpose of the Statute]

It is necessary first to determine the nature of the statute before us. The United States Supreme Court in the case of *United States v. Dotterweich*, (1943) 320 U. S. 277, said:

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

Also, in *United States v. Antikamnia Co.*, (1914) 231 U. S. 654 and *United States v. Schider*, (1917) 246 U. S. 519:

"The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it."

It is apparent, therefore, that the purpose of the law is the ever-insistent consideration in its interpretation. Congress by enacting it intended to promote honesty and fair dealing in trade and secure to the public pure



and wholesome food and drugs and there must be a reasonable construction to carry out the intention of Congress. This being "remedial legislation," the rule of liberal construction is to be followed irrespective of its penal provisions.

Mr. Justice Story in *Taylor et al. v. United States*, (1845) 3 How. 197, stated this principle as follows:

"In one sense, every law imposing a penalty or forfeiture may be deemed a penal law; in another sense, such laws are often deemed, and truly deserve to be called remedial. The judge was, therefore, strictly accurate, when he stated that 'It must not be understood that every law which imposes a penalty is, therefore, legally speaking, a penal law, that is, a law which is to be construed with great strictness in favor of the defendant. Laws enacted for the prevention of fraud, for the suppression of a public wrong, or to effect a public good, are not, in the strict sense, penal acts, although they may inflict a penalty for violating them.' And he added, 'It is in this light I view the revenue laws, and I would construe them so as most effectually to accomplish the intention of the legislature in passing them.' The same distinction will be found recognized in the elementary writers, as, for example, in Blackstone's Commentaries . . . and Bacon's Abridgement . . . and Comyns' Digest . . . and it is also abundantly supported by the authorities."

[*"Accompany" Defined*]

The word "accompany" has been defined in a number of cases. See *United States v. Lee*, (C. C. A. 7, 1942), 131 F. (2d) 464; *United States v. Research Laboratories, Inc.*, (C. C. A. 9, 1942), 126 F. (2d) 42, certiorari denied 317 U. S. 656; *United States v. 7 Jugs, etc., Dr. Salsbury's Rakos*, (D. C. Minn. 1944), 53 F. Supp. 746. An excellent analysis was made by District Judge Joyce in the *Rakos* case *supra*. He said:

"The word 'accompany' as used in Section 201 (m) (2) was said in *United States v. Lee*, 7 Cir. 1942, 131 F. (2d) 464, 466, 143 A. L. R. 1451, to mean: 'The word "accompany" is not defined in the Act, but we observe that among the meanings attributed to the word are "to go along with," "to go with or attend as a companion or associate," and "to occur in association with," Webster's New International Dictionary, 2d Ed.' Naturally, the meanings of accompany will vary in connection with subject matter. 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there

'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (*United States v. Lee*, 131 F. (2d) at page 466), the booklets here involved should be scrutinized from this viewpoint. \* \* \*

"The stipulation clearly shows that the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers in Achilles' territory. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. There was actual, physical association together in the stores of dealers and actual distribution together in connection with purchases by farmers. It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at different times, over a different route and were received at different time from the booklets should not be permitted to confuse or obscure the substance of the matter. \* \* \*

"What is vital are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary 'misbranded' status under Sec. 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control."

[*Interpretation of Statute*]

It is contended by defendant that the above cited cases were brought under libels of information for the condemnation of the articles involved; that these were civil proceedings; that the present case involves the criminal aspects of the statute and the definition should therefore be differently construed. To adhere to defendant's construction would result in a strange situation wherein under the same statute and the same section, a single word would have a different meaning dependent only on the nature of the action brought. This interpretation would defeat the enforcement of the statute and the court cannot subscribe



to such a proposition. Furthermore, the element of forfeiture in a statute is as much a penal provision as is the one imposing a penalty.

[*Conclusions*]

These booklets were shipped by the defendant. The drugs and booklets were sent to the same consignee. They were displayed and were intended to be distributed in

relation to the drug. The booklets, pamphlets or circulars were false and misleading.

From the evidence and proof in the trial of this case, the court finds the defendant Lelord Kordel guilty of violating the misbranding provisions of the Act. As to the defendant, Laura Kordel, the court is of the opinion the evidence is insufficient to support a conviction and she is therefore discharged.

**UNITED STATES v. CROWN RUBBER SUNDRIES CO., A  
PARTNERSHIP; AND JOSEPH LADER,  
AN INDIVIDUAL**

United States District Court for the Northern District of Ohio, Eastern  
Division. No. 18712. July 12, 1946. 67 F. Supp. 92.

The case involved a prosecution for shipping defective prophylactics in interstate commerce. Defendants had received the merchandise in bulk, had repacked it in individual containers bearing defendants' labels, and had shipped the product to their own customers. Defendants relied on a guaranty under the Act from the manufacturers. No person may rely upon any guaranty unless, in introducing the product into interstate commerce, he acted merely as a conduit through which the merchandise reaches the consumer.

Sections 201 (h), 301 (a), 303 (c), 501 (c), 502 (a), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act is to protect the consumer. Public policy casts upon those who introduce food, drugs, and cosmetics into interstate commerce the duty of rigid inspection. They are charged with absolute responsibility for the proper branding of their products.

Sections 301 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

The protection of the exemption clause of the statute does not include within its ambit those who, in any way, handle or process the product to which the guaranty attaches.

Sections 301 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

The guaranty can be received in good faith only if the shipper passes the product on in the same form as he receives it, without repacking it or subjecting it to any new hazards which were not present when the guaranty was given.

Sections 301 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

Since the defendants had repacked and relabeled the prophylactics and had shipped them in cartons bearing their own trade name, the defense of the guaranty was no longer available to them.

Sections 301 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

Don C. Miller, U. S. Attorney, for plaintiff.

Donald Gottswald, Akron, Ohio, and Roy C. Scott, Cleveland, Ohio, for defendants.

[*Matter for Decision*]

FREED, District Judge: The matter for decision involves the interpretation of Title 21, U. S. C. A., § 333 (c).

What is the extent of the immunity granted by this section to a distributor, who has branded and sold a product relying upon

a guaranty of compliance with the Federal Food, Drug, and Cosmetic Act, received from his manufacturer or seller in good faith?

[*Facts*]

The essential facts are not in dispute.

Crown Rubber Sundries Co., a partnership, and one of the partners, individually,



Joseph Lader, were charged in eight counts of an information alleging violation of Title 21, U. S. C. A. 331 (a) and Title 21, U. S. C. A. 352 (a) in the shipment and sale of rubber prophylactics which were, in fact, ineffective for prophylactic purposes because of the presence of holes and perforations in the devices.

*[Goods Were Adulterated and Misbranded]*

It is not disputed that the goods shipped in interstate commerce were adulterated and misbranded.

*[Defendants' Contention]*

The defendants rely solely upon the claim that they are free from guilt because they received a guaranty given them by the L. E. Shunk Latex Products Inc., the manufacturer, warranting that all the merchandise complied with the provisions of the Pure Food, Drug, and Cosmetic Act, and authorizing them to make the same guaranty to their distributees.

*[Defendants Repacked Goods]*

The undisputed facts show that the defendants received the merchandise in bulk, that they repacked the prophylactics in individual containers bearing their own labels and shipped them to their own customers. There was some evidence tending to show that the merchandise was acquired by the purchase of a wholesale business which had in stock the prophylactics which the original owner had purchased from the Shunk Company.

*[Purchase Not Made Directly from Manufacturer]*

Since the purchase was not made directly from the manufacturer, it is questioned whether the guaranty made to these defendants could inure to their benefit. It is urged by the Government that the guaranty which affords a defense is only one which is made to him who purchases directly from the guarantor.

*[Real Issue Involved]*

Although the court is of the opinion that the Government's contention in this regard is correct, the real issue is whether the defense of the guaranty, as a matter of law, can be made under the state of the evidence which is not in dispute.

Assuming, for the purpose of the instant case, that the defendants did have a right to rely upon a guaranty received from someone

other than the person from whom they purchased the merchandise, the question remains whether the guaranty affords a defense under the statute.

The decided cases have not dealt with the question here raised. The report of the Congressional committees throws no light upon the intent of Congress as affects the immediate issue.

*[Report of Congressional Committee]*

The effect of the guaranty, in the Committee's report, is touched upon briefly as affording protection to a manufacturer who ships his products to distant processors, who, in turn, package and label the finished merchandise. The Committee's report indicates it was the intent of Congress to relieve the manufacturer of the effect of violations of the Act that result from the processing of his products by others for whom the manufacturer should not be liable.

Neither the reported cases, nor the Committee's report, deals with the question of the defense available to the shipper who holds a guaranty from the manufacturer.

*[Guaranty Does Not Protect Processor]*

It is fundamental that the purpose of the Act is to protect the consumer. Public policy casts upon those who introduce foods, drugs, and cosmetics into interstate commerce the duty of rigid inspection. They are charged with absolute responsibility for proper branding of their products. Public safety demands of them not only extreme care, but definite assurance of the quality of their products.

It is the judgment of this court that no person may rely upon any guaranty unless, in introducing the product into interstate commerce, he has acted merely as a conduit through which the merchandise reaches the consumer.

The protection of the exemption clause of the statute does not include within its ambit those who, in any way handle or process the product to which the guaranty attaches, if one has been given.

The guaranty can be received in good faith, within the meaning of the statute, only if the shipper passes the product on in the same form as he receives it, without repacking it or subjecting it to any new hazards of adulteration or failure which were not present when the original guaranty upon which he relies was given.

The facts in this case show the prophy-



lactics were purchased by the defendants in bulk and that they repackaged and re-labeled them. They shipped them in cartons bearing their own trade name.

When this state of facts appears, in the judgment of the court, as a matter of law, the defense of the guaranty no longer is available to the defendants.

Such an interpretation, the court believes, would be in accord with the intent of Con-

gress, as reflected both by the general purpose of the Act and the language of the Committees in treating the extent of the defense available to the manufacturer.

Since the defense of the guaranty is not available to the defendants, and since the evidence establishes every other element of the offenses charged, it is the judgment of the court that they must be found guilty of the violations charged in the information.

## ALBERTY v. UNITED STATES

United States Circuit Court of Appeals for the Ninth Circuit. No. 11,338.

January 31, 1947. 159 F. 2d 278.

Reversing 65 F. Supp. 945. See page 315.

In a prosecution for shipping a misbranded drug in interstate commerce, the information charged that the false accompanying literature had been shipped more than two months prior to the drug. The information did not allege that the literature was to be placed with the drug or used together with it by the consignee. The bald statement in the information that the literature had been shipped to the consignee 71 days before the drug was shipped did not charge the offense of causing it to be "accompanying" the drug's introduction into interstate commerce.

Sections 201 (g), 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Hauerken, Ames & St. Clair, San Francisco, Cal., and O'Conner & O'Conner, Los Angeles, Cal., for appellant.

Ernest A. Tolin, U. S. Attorney, Walter S. Birns and Tobias G. Klinger, Asst. U. S. Attorneys, William Strong, Special Asst. to the U. S. Attorney, all of Los Angeles, Cal., for appellee.

Before GARRECHT, DENMAN, and ORR, Circuit Judges.

### [*Nature of Appellant's Appeal*]

DENMAN, Circuit Judge: Appellant appeals from a judgment sentencing her to three years on probation for violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 331 (a).

The language of the information is that

" . . . : Ada J. Alberty . . . doing business . . . at Hollywood, Los Angeles, State of California, did . . . on or about April 18, 1944 *then and there*, in violation of the Act of Congress . . . 21 U. S. C. 331 (a),<sup>1</sup> unlawfully introduce and deliver for introduction into interstate commerce, from Hollywood, Los Angeles, State of California, to Kansas City, State of Missouri, consigned to Natural

Food Store, a certain consignment, to wit, a number of bottles containing a drug within the meaning of 21 U. S. C. 321 (g) (2) . . .

"That displayed upon written, printed, and graphic matter *accompanying said drug when introduced and delivered for introduction into interstate commerce*, as aforesaid, namely upon a number of leaflets entitled 'So it's You again, is it?' relating to said drug which said leaflets were shipped by the said Ada J. Alberty trading and doing business as 'Alberty Food Products' to said Natural Food Store *prior to the date of the shipment of said drug as aforesaid*, to wit, *on or about February 7, 1944*, were among other things the following statements: . . .

<sup>1</sup> There is another provision of the Act, 21 U. S. C. 331 (k), forbidding misbranding after the drug has passed through interstate commerce, as follows:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or

cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

This section has no application to a charge that at the moment of introducing the drug into interstate commerce the misbranding "then and there" occurred.



"That said drug, when introduced and delivered for introduction into interstate commerce, as aforesaid, was *then and there* misbranded within the meaning of the said act of Congress [21 U. S. C. 352 (a)], in that the statements aforesaid appearing in the leaflets entitled 'So it's You again, is it?,' *accompanying* said drug, as aforesaid were false and misleading in this, that said statements represented and suggested that said drug would be efficacious to restore color to gray hair and would be efficacious to prevent hair from turning gray; whereas in fact and in truth said drug would not be efficacious to restore color to gray hair and would not be efficacious to prevent hair from turning gray." (*Italics supplied.*)

[*Appellant's Contentions*]

Appellant demurred to the information on the ground that it does not charge an offense within the sections of the Federal Food, Drug, and Cosmetic Act, contending to the court below, as follows:

"The Act in question (Secs. 343-a and 352-a of Title 21, U. S. C.) provides that a food or drug shall be deemed to be misbranded 'if its labeling is false or misleading in any particular.' Another section of the Act (Sec. 321-m of Title 21, U. S. C.) defines the term 'labeling' to mean 'all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' . . ."

and that the labels did not accompany the drug within Section 321 (m).

The district court overruled the demurrer, thus ruling against appellant's contention that the literature did not accompany the drug when it was introduced into interstate commerce. Appellant assigns this ruling as error.

[*Provisions of Section 331 (a)*]

Section 331 (a) provides:

"Prohibited acts

"The following acts and the causing thereof are hereby prohibited:

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that *is adulterated or misbranded.*" (*Italics supplied.*)

It will be noted that the verb "is" is in the present tense. Section 331 (a) confines the offense to a misbranding at the "introduction or delivery for introduction into interstate commerce" as recognized in the information by the use of the words "then and there."

[*Labeling Defined*]

A drug is misbranded "If its labeling is false or misleading in any particular." 21 U. S. C. 352 (a). "Labeling" of an article is defined to mean "all labels . . . accompanying such article." 21 U. S. C. 321 (m).

[*Charge in Information*]

The information charges that the false labels were shipped by appellant to the Natural Food Store at Kansas City, Missouri, on February 7, 1944, that is, two months and eleven days before April 18, 1944, when the drug was "then and there" introduced into interstate commerce. It does not allege that the labels were to be placed with the drug or used together with it by the consignee. For all the information alleges, the labels may not have arrived in Missouri. Or they may have been destroyed. Or they may have been distributed to the prospective customers a month before the arrival of the drug in Missouri and hence never accompanied it there. Or they may have been used in connection with other drugs shipped and sold long prior to April 18, 1944, when the charged offense is alleged "then and there" to have been committed.

We do not think that the bald statement that the labels were shipped to the Missouri consignee seventy-one days before the drug was shipped charges the offense of causing them to be "accompanying" the drug's introduction into interstate commerce on or about April 18, 1944.

[*Other Cases Distinguished*]

Appellee cites our decision *United States v. Research Laboratories, Inc.*, (CCA-9), 126 F. 2d 42. In that case, a condemnation proceeding, the libel charged that the false circulars accompanied the drug into interstate commerce and all arrived at their common destination simultaneously. The information in the instant appeal alleges no such facts and, on the contrary, cannot be construed as charging that the drug and labels were in interstate commerce at the same time, much less introduced therein at the same time. *United States v. 7 Jugs of Dr. Salsbury's Rakos*, 53 F. Supp. 746, has similar facts and follows the *Research Laboratories* case.

Appellee also cites *United States v. Lee*, (CCA-7), 131 F. 2d 464. The complaint there sought an injunction because of an entirely different offense—the placing of the drug and false printed matter together *after* the interstate shipment in violation



of 331 (k), referred to in our footnote above. It in no way supports the information purported to be based upon the claimed violation of 321 (m) at the time of shipment, to which appellant demurred.

*[Act Must Be Strictly Construed in Criminal Proceeding]*

These three cases were civil proceedings and not criminal prosecutions. They construe the Act liberally. The question was raised at the hearing here whether in construing the Act as the basis of a criminal prosecution there should be a similar construction against the accused. Cf. the recent case of *Kraus & Bros., Inc. v. United States*, 327 U. S. 614, 621, construing in a criminal proceeding the Emergency Price Control Act which, like the Food, Drug, and Cosmetic Act, also afforded civil relief. There the Supreme Court states

"This delegation to the Price Administrator of the power to provide in detail against circumvention and evasion, as to which Congress has imposed criminal sanctions, creates a grave responsibility. In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must

be applied the same strict rule of construction that is applied to statutes defining criminal action . . ."

However, we think that, whatever the criterion of construction, the ordinary use of the word "accompanying" which we have here accepted is that applicable.

*[Information Ordered Dismissed]*

After overruling the demurrer, the case was tried on a stipulation of facts which stated that the shipment of labels was received by the consignee on February 11, 1944, and the drug on April 25, 1944, clearly establishing that the two did not accompany each other when introduced into interstate commerce nor at any time in that interstate transit. It was also stipulated that they were exhibited together in the consignee's store. Here there might be said to be accompaniment *after* the interstate commerce was completed, but nothing is stipulated as to appellant's then ownership or control of the drug and labels or her participancy in these later acts to bring her within 331 (k), a section not involved in the information.

The judgment is reversed, the case is remanded, and the information ordered to be dismissed.

## JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY, v. UNITED STATES

United States Circuit Court of Appeals for the Fifth Circuit. No. 11774.  
May 12, 1947. 161 F. 2d 629.

Reversing 67 F. Supp. 192. See page 319.

Reversed, 332 U. S. 689. See page 350.

The case involved prosecution of a retail druggist for removing 12 tablets from a 1000-tablet bottle of sulfathiazole tablets bearing the "prescription legend" and warnings, and selling them without requiring a doctor's prescription. The 1000-tablet bottle had been purchased by defendant from a wholesaler in the state where defendant had his place of business, but had theretofore been transported in interstate commerce. A moderately strict construction of Section 301 (c) of the Act would confine it to shippers and importers in interstate commerce, and proffers of sale by the latter.

Section 301 (c), Federal Food, Drug, and Cosmetic Act.

The words "the doing of any other act" in Section 301 (k) should be held to apply only to the holding for the first sale by the importer after interstate shipment.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The United States can prohibit the destruction of labeling under which interstate commerce occurred, in order to preserve the evidence of what was done during the interstate movement, but in the prosecution of the defendant the evidence had never been meddled with.

Sections 201 (b), 301 (k), Federal Food, Drug, and Cosmetic Act.



The court did not find the application of the words "any other act" in Section 301 (k) plain enough to make criminals of retail grocers and druggists who do not import but who break and sell intrastate from the imported packages without mutilating the labeling.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

J. Madden Hatcher and R. M. Arnold, both of Columbus, Ga., for defendant-appellant. Vincent A. Kleinfeld, Attorney, Department of Justice, Washington, D. C., and John P. Cowart, United States Attorney, Macon, Ga., for the United States.

Before SIBLEY, McCORD, and LEE, Circuit Judges.

[*Facts of Case*]

SIBLEY, Circuit Judge: Sullivan, a local retail merchant in Columbus, Georgia, was convicted under the Federal Food, Drug, and Cosmetics Act, 52 Stats. 1040, Sect. 301 (c) and (k), 21 U. S. C. A. § 331 (c) and (k) for selling to two federal inspectors two lots of twelve tablets each of sulfathiazole taken from a bottle on the shelves of his drug store which had contained 1,000 tablets. The facts as alleged in the information and stipulated or proven on the trial are these: Between Nov. 25, 1943, and March 15, 1944, Abbott Laboratories, doing business in North Chicago, Illinois, shipped in interstate commerce to Abbott Laboratories, at Atlanta, Georgia, a number of boxes containing bottles of drugs, one of them being this bottle of 1,000 tablets of sulfathiazole, which was duly labeled as such, with a caution that they are to be used only by or on the prescription of a physician, and with the name and Chicago address of Abbott Laboratories. This bottle so labeled was on Sept. 29, 1944, in Atlanta sold to Sullivan, and by him transferred in intrastate commerce to his pharmacy in Columbus, and placed on his shelves for retail sales to customers. On Dec. 13, 1944, the two lots of twelve tablets each were taken from the bottle, placed in pasteboard pill boxes, with only the word sulfathiazole (slightly misspelled) on them, and sold to the federal inspectors. The label on the bottle was not defaced or changed, and the bottle was seen and afterwards taken in charge by the inspectors. A motion to dismiss the information as not charging a federal crime, and one for a judgment of acquittal because none was proved, were overruled and this appeal taken.

[*Contentions*]

The general constitutionality of the federal Act under the commerce clause of the Constitution is admitted. The contentions are that the Act is not intended to operate on retail sales over the counter after interstate commerce has ended; by one who was

not the importer; that the language is not clear enough to make criminals of such sellers; and that if construed to apply to them the Act is to that extent beyond the power of Congress.

[*Commerce Involved*]

It will be noted that the only interstate commerce here involved is the transportation of bottles of drugs in boxes from Chicago to Atlanta at least nine months before the sales here in question. The boxes came to rest in Atlanta and were opened by the importer, Abbott Laboratories, and the bottles were put in their stock of drugs in Atlanta for sale. Over six months thereafter Sullivan bought one bottle, which is conceded to have been duly labeled, and put it into his stock of drugs at Columbus for retail sales, where the bottle stayed for three more months. If the criminal provisions relied on apply here, they apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of foods, devices and cosmetics, for all these are equally covered by these provisions of the Act. We are not able to conclude that the Act is to be so construed as to bring within these penal provisions most of the sales in all drug stores, beauty parlors, barber shops and retail grocery stores in the United States.

[*Purpose and Prohibitions of Act*]

The general purpose of the Act is declared in its simple title: "An Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes." Section 301 (c) prohibits, (under penalty by Section 303), "The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise." Sullivan clearly did not receive in interstate commerce any misbranded drug, nor did he



proffer delivery of any in interstate commerce. A moderately strict construction of this penal provision would confine it to shippers and to importers in interstate commerce, and proffers of sale by the latter. Sullivan was a party to intrastate sales only. Moreover since this bottle was at all times duly labeled and not misbranded, no one violated this provision by receiving or proffering delivery of it.

Section 301 (k) prohibits "The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The labeling here was not removed or mutilated; but an act was done with respect to the drug, to-wit, the removal of some of it from the labeled bottle and the placing of it in a box not sufficiently labeled under the Act, after shipment in interstate commerce and while the drug was held for sale, so that this portion of the drug became misbranded. Therefore in their broadest possible sense these words may include what happened. But we are of opinion that they ought not to be taken so broadly, but held to apply only to the holding for the first sale by the importer after interstate shipment. Since importation by merchants of all merchandise is for the very purpose of sale, the importation, as has always been held, remains incomplete till its purpose is thus realized. *Brown v. Maryland*, 12 Wheat. 419. The words of subsection (k), "held for sale after shipment in interstate commerce," naturally refer to this first sale by the merchant importer. It was this sale which was involved in *McDermott v. Wisconsin*, 228 U. S. 115, and in *Baldwin v. Seelig*, 294 U. S. 511, much relied on by the government. We do not doubt, however, that the United States can prohibit the destruction of the labeling under which interstate commerce occurred, by anyone at any time, in order to preserve the evidence of what was done during the interstate movement, as is fairly held in the *McDermott* case cited; but here this evidence was never meddled with, but went unaltered into the hands of the inspectors, and it shows a correct labeling. These main provisions of subsection (k) were fully complied with. The attempt here made is to extend subsection (k) so as to make criminal all retail sales from the interstate package, though made

clearly in intrastate commerce, unless the label on the interstate package which has been broken be reproduced on the retail package. We believe no grocer or druggist thus breaking an interstate package for a retail sale has understood this was necessary, and it is said this case is the first effort to apply the federal Act in this way. If the "holding for sale" is held to refer to all would-be sellers, no matter where or when or in what quantities, of all foods and drugs and cosmetics which at some time had moved in interstate commerce, the field of enforcement of the Act will be multiplied many times. The reason urged for so expanding it, to-wit, the protection of ultimate consumers, only makes another difficulty; for while Congress may regulate interstate commerce to any extent and almost for any purpose it thinks proper, this extended application would be really a direct regulation for police purposes of what is plainly intrastate commerce, which is the peculiar province of the State.

[*Georgia Laws*]

And the State of Georgia has not neglected her duty. Title 42 of the Georgia Code deals with the subject of selling and labeling foods, drugs and toilet articles, with several cooperative references to the federal laws and regulations, as in Sect. 42-110, 42-111; and 42-802, 42-806. Sections 42-701 and ff. regulate the dispensing of poisons, this legislation dating back to the year 1876. Sections 42-101 and ff. embody comprehensive laws on the subject of foods and drugs passed in 1906 and 1908. The Uniform Narcotic Drugs Act of 1935 is found in Sections 42-801 and ff. The Dangerous Drug Act of 1939 is in Sections 42-708 and ff. The last expressly covers the derivatives and compounds of sulfanilimide, and the label on the bottle here in controversy indicates that sulfathiazole is such, so that this Georgia Act applies to these sales, and Sullivan appears to have violated it here. It would seem the federal inspectors should have reported them to the Georgia inspectors. It is probable that other States have similar laws, reducing the need for Congress to interfere thus in intrastate commerce, if it has the power.

[*Regulation of Intrastate Commerce  
Not Intended*]

In passing this Act Congress in its title indicated that its main and direct concern was with "the movement in interstate commerce." Until that movement is complete



and the importer has sold his original packages the State cannot interfere. Congress regulated what the Constitution directly authorizes. There is no indication of any intention to regulate intrastate commerce because of any burdensome effect on interstate commerce. The talismanic expression "Affecting interstate commerce" is not used, as in the National Labor Relations Act passed shortly before. In interpreting and applying those words in *National Labor Relations Board v. Jones and Laughlin Steel Corp.*, 301 U. S. 1, the court was careful to point out the rule of construction of statutes that a construction will not be adopted that is of doubtful constitutionality, in this very matter of federal intrusion upon the domain of the States, saying at page 30: "We have repeatedly held that as between two possible constructions of a statute by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the Act. Even to avoid a serious doubt the rule is the same (citing numerous cases.)"<sup>1</sup> Also in *Federal Trade Commission v. Bunte Bros.*, 312 U. S. 349, we read: "The construction of § 5 urged by the Commission would thus give a federal agency pervasive control over myriads of local businesses in matters heretofore traditionally left to local custom or local law. . . . An inroad upon local conditions and local

standards of such far reaching import as is involved here, ought to await a clearer mandate from Congress." Much more ought unambiguous and clear words to be required when statutes creating criminal offenses are for construction. *United States v. Wiltberger*, 5 Wheat. 76; *United States v. Harris*, 177 U. S. 305; *Kraus v. United States*, 327 U. S. 614.

[Subsection (k) Not Applicable to Retailers  
Unless Labeling Mutilated]

The purpose of this Act being to regulate "movement in interstate commerce" of foods, drugs and cosmetics, and the general purpose of subsection (k) being to prohibit mutilation of the labeling on the packages which so moved, we do not find the proposed application of the *ejusdem generis* words "Any other act" plain enough to make criminals of retail grocers and druggists who did not import but who break and sell intrastate from the imported packages without mutilating the labeling.<sup>2</sup> We thus find it unnecessary to determine the constitutionality of the federal regulation of intrastates sales as here contended for, by denying that doubtful construction.

The judgment is reversed with direction to acquit the defendant below.

Judgment Reversed.

---

UNITED STATES v. WALSH, AN INDIVIDUAL TRADING  
AS KELP LABORATORIES

United States Supreme Court. No. 718, October Term, 1946.  
May 19, 1947. 331 U. S. 432.

The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. It is in that interstate setting that the various sections of the Act must be viewed.

Sections 201 (b), 301 (a), 901, Federal Food, Drug, and Cosmetic Act.

Section 301 (a) of the Act is directed to illegal interstate shipments, while Section 301 (h) is directed to the giving of a false guaranty. A guaranty as described in Section 303 (c) (2) may be used by interstate dealers in connection with either interstate or intrastate shipments, and the giving of a false guaranty is outlawed by Section 301 (h).

Sections 301 (a), 301 (h), 303 (c), Federal Food, Drug, and Cosmetic Act.

---

<sup>1</sup> *Schechter Poultry Corporation v. United States*, 295 U. S. 495, though not exactly in point, is enough to raise serious doubt in this case.

<sup>2</sup> *Armour and Co. v. Dakota*, 240 U. S. 510, and *Weigle v. Curtice Bros. Co.*, 248 U. S. 285, held that retail sales from broken interstate packages were not governed by the federal Food and

Drugs Act then in force but by the State law, partly for constitutional reasons; but the present Act differs enough to make these decisions probably not controlling here. In *United States v. Dotterweich*, 320 U. S. 277, the shipment of the repacked drugs was in interstate commerce and was prosecuted under Sect. 301 (a), and the construction of (k) was not involved at all.



Section 301 (h) definitely proscribes the giving of a false guaranty to one engaged wholly or partly in an interstate business, irrespective of whether that guaranty leads in any particular instance to an illegal shipment in interstate commerce.

Section 301 (h), Federal Food, Drug, and Cosmetic Act.

So construed, Section 301 (h) raises no constitutional difficulties. The Commerce Clause of the Constitution is not to be interpreted so as to deny to Congress the power to make effective its regulation of interstate commerce.

Section 301 (h), Federal Food, Drug, and Cosmetic Act.

George T. Washington, Theron L. Caudle, Robert S. Erdahl, Sheldon E. Bernstein, and Vincent A. Kleinfeld, for Government.

Miller, Higgs, Fletcher and Glen, for defendant.

MR. JUSTICE MURPHY delivered the opinion of the Court.

This appeal brings before us § 301 (h) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 1042, 21 U. S. C. § 331 (h), which prohibits the giving of a false guaranty that any food, drug, device or cosmetic is not adulterated or misbranded within the meaning of the Act.

[*Facts in Case*]

Appellee does business in San Diego, California, under the name of Kelp Laboratories. An information has been filed, charging appellee with having given a false guaranty in violation of § 301 (h). The following facts have been alleged: In February, 1943, appellee gave a continuing guaranty to Richard Harrison Products, of Hollywood, California, stating that no products thereafter shipped to the latter would be adulterated or misbranded within the meaning of the Act. On February 24, 1945, while the guaranty was in full force and effect, appellee consigned to Richard Harrison Products, at Hollywood, a shipment of vitamin products which were allegedly adulterated and misbranded—thereby making the guaranty false in respect of that shipment. Prior and subsequent to the date of the shipment, Richard Harrison Products was engaged in the business of introducing and delivering for introduction into interstate commerce quantities of the vitamin products supplied by appellee.

Appellee moved to dismiss the information on the ground that it did not state an offense. The argument was that § 301 (h) applies only to a guaranty that is false

relative to an interstate shipment, whereas the alleged shipment here was to a consignee within California, the state of origin, and there was no allegation that the consignee purchased the order for someone outside California or that it intended to sell the products in its interstate rather than its intrastate business. The District Court gave an oral opinion sustaining appellee's contention and granting the motion to dismiss. The case is here on direct appeal by the United States.

[*Interstate Setting of Federal Food, Drug, and Cosmetic Act*]

The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated and misbranded articles of the specified types. *United States v. Dotterweich*, 320 U. S. 277, 280. It is in that interstate setting that the various sections of the Act must be viewed.

[*Statutory Construction*]

But § 301 (h), with which we are concerned, does not speak specifically in interstate terms. It prohibits the "giving of a guaranty or undertaking referred to in section 303 (c)(2), which guaranty or undertaking is false," the only exception being as to a false guaranty given by a person who, in turn, relied upon a similar guaranty given by the person from whom he received in good faith the adulterated or misbranded article.<sup>1</sup> Nothing on the face of the section limits its application to guar-

<sup>1</sup> Section 301 (h) prohibits "The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address

of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false."



anties relating to articles introduced or delivered for introduction into interstate commerce. From all that appears, its proscription plainly extends to the giving of any false statutory guaranty, without regard to the interstate or intrastate character of the shipment in question, to those who are engaged in the business of making interstate shipments.

Nor do we find any interstate limitation of the type which appellee proposes in the reference made in § 301 (h) to § 303 (c)(2).<sup>2</sup> That reference is made simply to define the type of guaranty or undertaking, the falsification of which is prohibited by § 301 (h). Instead of spelling out the matter, § 301 (h) adopts the reference in § 303 (c)(2) to "a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect . . . that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act." The fact that § 303 (c)(2) relieves a holder of such a guaranty from the criminal penalties provided by § 303 (a) for violating § 301 (a) does not carry over the interstate limitation of § 301 (a) to § 301 (h). Section 301 (a) prohibits the introduction or delivery for introduction into interstate commerce of illicit articles,<sup>3</sup> and § 303 (c)(2) relieves one from the liabilities of such introduction if one has a guaranty or undertaking as therein described. Section 301 (h) has adopted that description for the entirely different purpose of informing persons what kind of a guaranty or undertaking may not be given falsely. In other words, § 301 (a) is directed to illegal interstate shipments, while § 301 (h) is directed to the giving of false guaranties. Guaranties as described in § 303 (c) (2) may be used by interstate dealers in connection with either interstate or intrastate shipments and those guaranties that are false are outlawed by § 301 (h).

It is true, of course, that the guaranty referred to in § 303 (c)(2) is one given for the purpose of protecting the dealer "in case of an alleged violation of section 301

(a)," thereby relieving him of liability if he reships adulterated or misbranded goods in interstate commerce. But where such a guaranty, as in this case, is given to a dealer regularly engaged in making interstate shipments and who may therefore have need of the guaranty, § 301 (h) imposes liability on the guarantor if that guaranty turns out to be false. And that liability attaches even where the particular shipment which renders the guaranty false is not alleged to have been an interstate one.

[*Comparison with 1906 Act*]

It is significant that § 301 (h) had no counterpart in the predecessor statute, the Food and Drugs Act of 1906, 34 Stat. 768. Under § 9 of that Act, a dealer could not be prosecuted for shipping adulterated or misbranded articles in interstate commerce if he had a guaranty of a type similar to that referred to in the present statute. If there were such a guaranty, the guarantor was subject to the penalties which would otherwise attach to the dealer. The result was that the guarantor was not liable on account of a false guaranty unless the dealer had shipped the prohibited article in interstate commerce. *Steinhardt Bros. & Co. v. United States*, 191 F. 798, 800; *United States v. Charles L. Heinle Specialty Co.*, 175 F. 299, 300-301. There was no liability for issuing a false guaranty as such to one engaged in an interstate business. But in the 1938 Act, Congress added a new liability in the form of § 301 (h), making the guarantor liable for giving a false guaranty of the type referred to in § 303 (c)(2). We find it impossible to say that the framers of the 1938 Act added § 301 (h) for the useless purpose of achieving the same result as had been reached under the 1906 Act without such a provision.

[*Guarantor Held Liable*]

We thus conclude that § 301 (h) definitely proscribes the giving of a false guaranty to one engaged wholly or partly in an interstate business irrespective of whether that guaranty leads in any particular instance to an illegal shipment in interstate

<sup>2</sup> Section 303 (c) (2) provides that no person shall be subject to the penalties of § 303 (a) "for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act,

designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce."

<sup>3</sup> Section 301 (a) prohibits "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."



commerce. Such a construction is entirely consistent with the interstate setting of the Act. A manufacturer or processor ordinarily has no way of knowing whether a dealer, whose business includes making interstate sales, will redistribute a particular shipment in interstate or intrastate commerce. But if he guarantees that his product is not adulterated or misbranded within the meaning of the Act, he clearly intends to assure the dealer that the latter may redistribute the product in interstate commerce without incurring any of the liabilities of the Act. And the dealer is thereby more likely to engage in interstate distribution without making an independent check of the product. The possibility that a false guaranty may give rise to an illegal interstate shipment by such a dealer is strong enough to make reasonable the prohibition of all false guaranties to him, even though some of them may actually result only in intrastate distribution. By this means, some of the evils which Congress sought to eliminate are cut down at their source and the effectiveness of the Act's enforcement is greatly enhanced.

*[No Constitutional Difficulties Arise]*

So construed, § 301 (h) raises no constitutional difficulties. The commerce clause of the Constitution is not to be interpreted so as to deny to Congress the power to make effective its regulation of interstate commerce. Where that effectiveness depends upon a regulation or prohibition attaching regardless of whether the particular transaction in issue is interstate or intrastate in character, a transaction that concerns a business generally engaged in interstate commerce, Congress may act. Such is this case.

The judgment of the District Court is accordingly *Reversed*.

**Dissenting Opinion**

MR. JUSTICE JACKSON, dissenting: Stretch the Food and Drugs Act as we will, I cannot make it cover this charge as a crime. The statutory scheme is to make a crime of "The introduction or delivery for introduction into interstate commerce" of adulterated or misbranded goods. 52 Stat. 1042, 21 U. S. C. § 331 (a) and (d).

But since many shippers buy goods of others and do not know their precise ingredients, Congress allowed an escape for the violator, provided he acted in good faith and could trace the responsibility to another. This he must do by producing a signed

guaranty or undertaking, and the statute requires that it shall be conditioned "to the effect, *in case of an alleged violation of § 331 (a)*, that such article is not adulterated or misbranded . . . or to the effect, *in case of an alleged violation of § 331 (d)*, that such article is not an article" forbidden shipment by stated paragraphs of the Act. (Italics added.) 52 Stat. 1043, 21 U. S. C. § 333 (c).

It will be noticed that Congress not only provided but repeated that the statutory bond required is "in case of an alleged violation" by introducing or delivering for introduction of goods in interstate commerce. No such violation has been alleged here; these goods were never introduced or delivered for introduction into interstate commerce. But the Court seems to think it is enough that there are some grounds for expecting that this crime possibly, or probably, or perhaps pretty certainly, would eventually be committed.

Of course, if the assured had committed this offense and had fallen back on the guarantor, the statute which reached the assured would not be sufficient. To punish the responsible person, it was made a crime to give a false guaranty "referred to in" the statute. 52 Stat. 1042, 21 U. S. C. § 331 (h).

The Government now seeks to exact criminal responsibility on a guarantee, expressly conditioned only "in case of violation," in a case of no violation. Until a violation is alleged, the guaranty plays no statutory role at all. It might afford a cause of action if false, but that is quite different from making it a crime. For it is no guaranty at all for criminal prosecution purposes if violation of neither § 331 (a) nor § 331 (d) is alleged. The statute requires such violation to be alleged only, not proved, in order to put the guarantor rather than the assured to the proof. This is the only instance I recall where the guarantor is liable when there is no breach of the condition of the bond. The whole plan was to have a substituted liability in case the violator of the Act became such in good faith. This decision makes a new, independent and original liability where there has been no alleged violation by moving the goods in interstate commerce.

I do not think we should take such liberties in expanding criminal statutes in which the sovereign once was considered under a duty to be explicit and the subject entitled to the doubt.



**UNITED STATES v. PARFAIT POWDER PUFF CO., INC.**

United States Circuit Court of Appeals for the Seventh Circuit. No. 9269.

November 4, 1947. 163 F. 2d 1008.

Certiorari denied, 332 U. S. 851 (1948).

The defendant, engaged in the manufacture and sale of cosmetics, entered into a contract with Helfrich whereby Helfrich agreed to manufacture, place in packages, and distribute to defendant's customers hair lacquer pads. Defendant supplied Helfrich with jars, caps, labels, etc.; and Helfrich impregnated the pads with a shellac lacquer, placed them in labeled jars bearing defendant's name, shipped the packages in accord with directions furnished by defendant, and rendered bills to defendant. A sample submitted by Helfrich was tested by defendant and found satisfactory; later, without defendant's knowledge, Helfrich substituted a gum which was deleterious. It was held that the defendant was engaged in procuring the manufacture and distribution of the article in interstate commerce and could be held criminally liable therefor.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

The person who brings goods into commerce, by whatever means or implements, is bound to see that the commodity is not beyond the pale of the Act. One who owes a duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law, if the nonperformance of such duty is a crime.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The defendant was not entitled to exemption under Section 303 (c) (1) since it was not within the class mentioned in the section; it had not received the article complained of in interstate commerce.

Sections 301 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

Harry H. Ruskin and Joseph Rosenbaum, both of Chicago, Ill., for appellant.

Otto Kerner, Jr., U.S. Atty., Robert C. Eardley, Theron L. Caudle, Asst. Atty. Gen., J. Albert Woll, U.S. Atty., Northern Dist. of Ill., all of Chicago, Ill. (Vincent A. Kleinfeld, Atty., Dept. of Justice, and Arthur A. Dickerman, Atty., Federal Security Agency, both of Washington, D.C., of counsel), for appellee.

Before EVANS, SPARKS, Circuit Judges, and LINDLEY, District Judge.

LINDLEY, District Judge: Defendant appeals from a judgment of conviction of a charge of violation of Section 301 (a) of the Federal Food, Drug, and Cosmetic Act, (21 U. S. C. A. § 301, *et seq.*) entered after trial without a jury, largely upon stipulated facts.

*[Applicable Sections]*

Section 301 (a) prohibits introduction into interstate commerce of any food, drug, device, or cosmetic which is "adulterated or misbranded." Anyone violating this enactment is subject to prosecution under Section 303 (a), reading: "Any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; \* \* \*." There is

no dispute that the cosmetics involved, hair lacquer pads, were adulterated in that they contained a substance which rendered them deleterious in use under the conditions prescribed on their labels, or that they were introduced into interstate commerce.

*[Issue]*

The only issue here, whether the defendant was rightfully held responsible for the violation, must be determined upon the facts. Defendant, engaged in the manufacture and sale of cosmetic products, in 1943, entered into a contract with Helfrich Laboratories whereby the latter agreed to manufacture, place in packages and distribute to defendant's customers hair lacquer pads. Defendant supplied Helfrich with jars, caps, labels, display cards, flannel pads and shipping containers. Helfrich impregnated the



pads with a shellac lacquer, placed them in labeled jars bearing defendant's name, shipped the packages, in accord with shipping directions furnished by defendant, consigned by defendant to its purchasers as consignees, and rendered bills to defendant for the commodity.

The sample submitted by Helfrich, when the arrangement was first made, was tested by defendant and found satisfactory. Later, without defendant's knowledge, so far as this record discloses, Helfrich substituted for shellac in the lacquer, a gum, for the reason, as it claimed, that it was impossible to obtain shellac. This element proved to be deleterious in use. As soon as defendant learned of the substitution it forbade use of the gum.

[*Defendant's Contention*]

In this situation, it is defendant's position that the violation was not that of itself but that of Helfrich. It argues that Helfrich was not its agent, but an independent contractor, for whose acts it is not responsible. But we are not concerned with any distinction between independent contractors and agents in the ordinary sense of those words. It is clear that defendant was engaged in procuring the manufacture and distribution of the article in interstate commerce. It saw fit to create out of Helfrich's activities in its behalf an instrumentality and to avail itself of the acts of that instrumentality, which effected an introduction into commerce of an adulterated article violative of the standards fixed by the Act. This we think it could not do without incurring the criminal penalty imposed by the statute. The liability was not incurred because defendant consciously participated in the wrongful act, but because the instrumentality which it employed, acting within the powers which the parties had mutually agreed should be lodged in it, violated the law. The act of the instrumentality is controlled in the interest of public policy by imputing the act to its creator and imposing penalties upon the latter. *New York Central and Hudson River Railroad Company v. United States*, 212 U. S. 481.

[*Statute for Public Protection*]

In *United States v. Balint, et al.*, 258 U. S. 250, 254, the court directed attention to authorities approving legislation in aid of maintenance of a public policy, prohibiting and punishing particular acts, commenting that "he who shall do them shall do them at his peril and will not be heard to plead

in defense, good faith or ignorance" and proceeding as follows: "Congress weighed the possible injustice of subjecting an innocent seller to a penalty against the evil of exposing innocent purchasers to danger from the drug, and concluded that the latter was the result preferably to be avoided." And in the comparatively recent case, *United States v. Dotterweich*, 320 U. S. 277, the court said:

"The offense is committed \* \* \* by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrong-doing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

In other words, when defendant engaged in manufacture and distribution of cosmetics in commerce, there was in force this statute, enacted as a matter of public policy for the protection of the purchasing public. Defendant knew that the goods would pass into commerce. It knew that if those goods violated the provisions of the Act, liability would be incurred. This liability it could not shift to the instrumentality which it had created for the purpose of accomplishment of the completed transaction of manufacture, distribution and sale. Rather defendant was bound to see that its product, when introduced into commerce, was not antagonistic to and violative of the sovereign will, which, expressed in the act of Congress, enters into and becomes a part of all contracts relating to the production and distribution of articles in commerce. The person who brings goods into commerce, by whatever means or implements, is bound to see that the commodity thus put in commerce is not beyond the pale of the legislative act. In other words, one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law, if the non-performance of such duty is a crime. De-



defendant may not put into operation forces effectuating a placement in commerce of a prohibited commodity in its behalf and then claim immunity because the instrumentality it has voluntarily selected has failed to live up to the standards of the law. *Cummer-Graham Co. v. Straight Side Basket Corp.*, 142 F. 2d 646 (C. C. A. 5); Anno. 152 A. L. R. 761; *John Griffiths & Son Company v. National Fireproofing Co.*, 310 Ill. 331, 38 A. L. R. 559; *U. S. v. Wilson*, 59 F. 2d 97; *U. S. v. Buchanan*, 9 F. 689; *Weeks v. U. S.*, 224 F. 64 (C. C. A. 2); 1 Burdick Law of Crime, p. 232, *et seq.*

[*Alleged Exemption*]

Defendant makes the further contention that it is exempt from prosecution by virtue of Section 303 (c) of the Act. Section 303 (a) provides that any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine. Section 303 (c) provides that "no person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith," unless certain conditions precedent are complied with. Defendant insists that it is a person who has "received in interstate commerce" the deleterious article within the meaning of this provision. But the weakness of the contention is that defendant is not within the class mentioned in Section 303 (c). It has not received in interstate commerce the article complained of. On the contrary, it is the moving force in the procurement of introduction of the article into commerce. The

facts will not justify the strained construction that when Helfrich delivered the goods to carriers in behalf of defendant as consignor, addressed to its purchasers as consignees, defendant thereupon received the goods in interstate commerce within the meaning of the Act. Rather than having received the goods in commerce, defendant in fact caused them to be placed in commerce. This is apparent when we consider the purpose of this provision. It is clear that it was designed to protect innocent dealers who receive goods shipped in interstate commerce. Thus, in Senate Report No. 493, 73d Cong. 2d Sess., accompanying S. 2800, the Senate Committee reported as follows: "The existing law provides for a guaranty whereby a dealer who buys on faith may be protected from liability under the law. This provision has safe-guarded innocent dealers and has been extremely useful in fixing responsibility on guilty shippers. It would be continued in effect by paragraph (e). The bill affords in this paragraph further protection to the innocent dealer who distributes goods he has received from interstate sources. If he has failed to secure a guaranty he can escape penalties by furnishing the records of interstate shipment, thus allowing the prosecution to lie solely against the guilty shipper." It is clear, we think, that the Act was intended to furnish protection to innocent receivers of goods shipped to them in interstate commerce in violation of the Act and not to consignors of such goods, such as defendant.

The judgment is affirmed.

---

UNITED STATES v. KORDEL

United States Circuit Court of Appeals for the Seventh Circuit. No. 9151.

November 6, 1947. 164 F. 2d 913.

Affirming 66 F. Supp. 538. See page 328.

Affirmed, 335 U. S. 345. See page 382.

The defendant was prosecuted for having introduced into interstate commerce drugs whose labeling bore false and misleading therapeutic claims. The alleged misbranding was contained in pamphlets, circulars, and a display card, often shipped separately to the consignee apart from the drugs. It is now generally held that in order to support a misbranding charge it is not necessary that the matter alleged to accompany the product be shipped in the same container.

Sections 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.



Labeling and advertising are not mutually exclusive; and the placing of a mailing permit or price tag on literature cannot insulate one from liability for introducing drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him.

Sections 201 (m), 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The evidence was clear that the booklets involved were actually displayed on racks close to the counter where the products were sold by the consignee, and that they were necessary to inform the purchasing public of the uses to which the products were to be put.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

The correct concept of "accompaniment" is one of a commercial or business association. The test is not one of physical contiguity but of textual relationship. Thus viewed, the products and literature involved were interdependent because, without the latter, the former lacked the labeling necessary to inform the purchasing public of their uses and purposes.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

Because the literature was shipped by the defendant, or at his order, to the same consignees as the products, related to the products, and was intended to be distributed in relation to them, it did accompany the products in interstate commerce.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

While the claims made for the products were fantastic, they tended to lull people into a false sense of security, and, since the accompanying literature embodied such misleading representations, it constituted misbranding.

Sections 201 (m), 502 (a), Federal Food, Drug, and Cosmetic Act.

Courts have for a long time been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction.

Title, Federal Food, Drug, and Cosmetic Act.

The court held that the evidence was sufficient to sustain the charge against the defendant beyond a reasonable doubt.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

Since Section 303 (a) provides that a violator shall be guilty of a misdemeanor and shall be subject to imprisonment for not more than one year, unless he has been convicted of a prior offense, there was no necessity for prosecution by indictment.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

James W. Breen, Chicago, Ill., for appellant.

Otto Kerner, Jr., U.S. Atty., and Robert C. Eardley, both of Chicago, Ill., William W. Goodrich, of Washington, D.C., Theron L. Caudle, Asst. Atty. Gen., and J. Albert Woll, U.S. Atty., of Chicago, Ill. (Vincent A. Kleinfeld, Atty., Dept. of Justice, of Washington, D.C., of counsel), for appellee.

Before EVANS and SPARKS, Circuit Judges, and LINDLEY, District Judge.

SPARKS, Circuit Judge: Appellant was charged by three criminal informations with violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. sections 301, *et seq.* He waived jury trial and, upon trial by the court, was found guilty and fined \$200 on each of the twenty counts contained in the three informations. The

appeal is from those judgments.

[*Alleged Errors*]

The facts as to the shipping of the drugs and the literature alleged to constitute the misbranding charged in the informations were entirely stipulated. Error is asserted in the court's finding that that literature



"accompanied" the drugs in interstate commerce in the purview of the Act prohibiting the introduction or delivery for introduction of any drug that is misbranded. Other contested issues relate to the degree of proof necessary in a criminal proceeding under the Act, whether the Act should be strictly construed, and whether prosecution should have been by indictment rather than by information.

[Facts]

Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through "health food" stores. The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage, and, in some cases, the alleged daily minimum requirement of the vitamins or minerals therein. Otherwise they give no indication as to their intended uses.<sup>1</sup> The misbranding charged is contained in a number of printed pamphlets and circulars, and one display placard. The modes of distribution of this literature differed as charged in the various counts of the informations. In some cases it was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively.

[Applicable Sections of the Act]

Section 301 of the Food and Drugs Act as amended in 1938, 21 U. S. C. A. sec. 331, prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded; section 502, 21 U. S. C. A. sec. 352, provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201 (m), 21 U. S. C. A.

sec. 321 (m), defines the term "labeling" to include all labels and other written, printed, or graphic matter "(1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container (*United States v. Research Laboratories*, 126 F. 2d 42), nor even that it be shipped simultaneously (*United States v. Lee*, 131 F. 2d 464; *United States v. 7 Jugs* \* \* *Rakos*, 53 Fed. Supp. 746; *United States v. Paddock*, 67 Fed. Supp. 819).

[Appellant's Contentions]

Appellant contends that the cases referred to are not applicable for the reason that all involved civil proceedings rather than criminal, and further, that the literature here involved was not only not shipped in the same carton with the products in all cases, but neither was it intended by him that product and literature should be placed together by the dealer to whom they were sent. His theory apparently is that the matter was not intended for labeling, but for advertising. He points to the fact that all of the printed matter was intended either to be mailed out or to be sold, as indicated by the fact that with the exception of the one display placard, each piece either contained a price mark or a mailing permit with space for address. This, he contends, supports his theory that product and literature were not to be distributed together, hence cannot be said to accompany each other.

[Labeling and Advertising Not Mutually Exclusive]

We find two answers to this contention. In the first place, labeling and advertising are not mutually exclusive, and the same matter may serve both purposes. As the Court of Appeals for the Ninth Circuit states in *United States v. Research Laboratories*, 126 F. 2d 42, "Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes

<sup>1</sup> The articles involved in the three informations are named "Gotu Kola," "Minerals plus Chlorophyll and Vitamin D," "Cetabs," "Fenu-greek Tea," "Fero-B-Plex," "Bolax," "Ormo-

tabs," "Ribotabs," "Kordel Tablets," "Everm," "Kordel A," "Garlic Plus," "Niamin," and "Sarsaparilla Tea."



advertising." See also *United States v. Paddock*, 67 Fed. Supp. 819. In the second place, the placing of the mailing permit or the price tag on the literature cannot insulate appellant from liability for introducing the drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him. The evidence is clear that the booklets were actually displayed on racks close to the counter where the products were sold and that they were necessary to inform the purchasing public of the uses to which these products were to be put.

[*Accompaniment*]

We agree with appellee that "the correct concept of 'accompaniment' is one of a commercial or business association." As stated in the *Rakos* case, *supra*, "misbranding has true significance only in terms of the consumer. \* \* \* 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there 'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (citing the decision of this court in *United States v. Lee*, *supra*) the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products \* \* \* have none."

[*Textual Relationship*]

We, too, are convinced that the test is not of physical contiguity but of textual relationship. Viewed thus, the products and literature here involved were interdependent because without the latter, the former lacked the labeling necessary to inform the purchasing public of their uses and purposes—it is significant that the labels printed on the immediate containers did not indicate the purposes for which the articles were to be used. Hence, the literature was intended and essential to explain the alleged uses of the products. They constituted a supplement to the label physically attached to the product container. One of the health food dealers in whose store the Kordel products were sold admitted that if he were buying one of the products he would have to go to "reliable sources" to know to what use to put the product. Presumably those reliable sources were the booklets displayed in racks close by the counter where the drugs

were dispensed or lying on the counters where they were available to the public and could be picked up and examined. Some also were wrapped with merchandise or handed to customers.

We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be distributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. To hold otherwise would be to permit evasion of the Act by the very easy subterfuge of printing a purchase price or a mailing permit on advertising matter otherwise unquestionably accompanying products into interstate commerce.

[*Misrepresentations in the Literature*]

With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, "Nutrition Guide," and "What you can do about relieving the agonies of Arthritis," were written by appellant who, in the latter, is described as "America's leading vitamin and diet expert." "Health Today, Spring 1945," is edited by the same "famous nutrition and vitamin authority." While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair and eyes, normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous breakdown, sterility, and paralysis.



Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while delay in correct diagnosis and treatment for those conditions might render the treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. He branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were harmful, replied, "They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy."

All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act.

[*Public Health Statutes Liberally Construed*]

Appellant contends that, since the current proceedings are criminal, he is entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt. Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in *Sutherland on Statutory Construction*

(Vol. III, sec. 7202), "The public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties." To the same effect is the ruling in *United States v. Dotterweich*, 320 U. S. 277, where the Court said, "The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."

We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt.

[*The Alberty Case*]

Appellant strongly relies upon *Alberty v. United States*, 159 F. 2d 278, to sustain his proposition that booklets and the like, not shipped at the time of the articles, do not "accompany" the article when they are introduced or offered for introduction into interstate commerce, and consequently cannot "then and there" misbrand them. The Circuit Court of Appeals for the Ninth Circuit there reversed an order overruling a demurrer to an information and remanded the cause with directions to dismiss the information. It distinguished three of the cases to which we have referred (*United States v. Research Laboratories*, *United States v. 7 Jugs \* Rakos*, and *United States v. Lee*), on the ground that all involved civil proceedings and construed the Act liberally. We have already indicated that under the authorities cited, we do not consider the distinction applicable to the construction of the statute here involved. To the extent that the court limits the definition of the word "accompany" to mean only physical association and contiguity, we do not agree with its reasoning and are convinced that it is not in harmony with those authorities.

[*Prosecution*]

We find no merit in appellant's contention that he should have been prosecuted by indictment rather than by information. Section 303 (a) upon which the informations were based (21 U. S. C. A. sec. 333 (a))



provides that any person violating any of the provisions of section 201 shall be guilty of a misdemeanor, and subject to imprisonment for not more than one year or a fine of \$1,000 or both, unless he has already been convicted of a prior offense under the same section. The charges were brought under this section. That being the case,

there was no necessity for prosecution by indictment. See *United States v. Wells Co.*, 186 Fed. 248 (holding violation of the 1906 Food and Drugs Act not an infamous crime). See also *Falconi v. United States*, 280 Fed. 766, and cases there cited.

Judgments affirmed.

## UNITED STATES v. ROMA MACARONI FACTORY ET AL.

United States District Court for the Northern District of California, Southern Division. No. 31035. December 10, 1947. 75 F. Supp. 663.

The defendants were prosecuted for having introduced into interstate commerce a food paste which was adulterated under Section 402 (a)(3) and (4). Intent, or lack of knowledge as to the adulteration, is not a part of the offense charged.

Sections 301 (a), 303 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

The purpose of the Act is to protect the consumer.

Title, Federal Food, Drug, and Cosmetic Act.

The Act does not provide that persons shall avoid putting filthy food substances into interstate commerce, or preparing such substances under unsanitary conditions, if it is possible; it provides that it shall not be done at all. A party who cannot prepare food products under sanitary conditions must cease putting such products into interstate commerce.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The word "filthy," as used in the Act, should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

### [Violations Charged in the Indictment]

HARRIS, District Judge: In this matter the grand jury found its indictment charging the defendants Roma Macaroni Factory, a corporation, and Albert Martinelli, superintendent, and Dominic Louis Gerbo, manager, as defendants, with the alleged violation of the Federal Food, Drug, and Cosmetic Act, Title 21, U. S. C. A., § 331. It appears from the indictment, in the charging part thereof, that the defendants did on or about the 27th day of December, 1946, in violation of the Federal Food, Drug, and Cosmetic Act unlawfully cause to be introduced, and deliver for introduction into interstate commerce at San Francisco, State of California, for delivery to Reno, State of Nevada, consigned to Brunetti & Patrone, a number of cases, each containing paste, a food within the meaning of the Act.

It is further charged that the defendants caused to be introduced and delivered for introduction into interstate commerce, food

adulterated within the meaning of the Act, in that it consisted in part of a filthy substance, by reason of the presence in said food of insect fragments, rodent hair fragments, hair resembling rodent hair and unidentified hair.

It is further charged that when the food was caused to be introduced and delivered for introduction into interstate commerce, it was adulterated and that it had been prepared and packaged, under unsanitary conditions, whereby it may have become contaminated with filth.

### [Previous Conviction]

Further, it appears, from the indictment, that on June 3, 1946, the Roma Macaroni Factory and Albert Martinelli and Dominic Louis Gerbo were convicted in this court of violation of the Federal Food, Drug, and Cosmetic Act, Docket No. 301256, which conviction had become final before the violation hereinbefore alleged was committed.



The defendants before the bar entered their pleas of not guilty to the charges, and each of them, embraced in the indictment. It appears that in connection with said prior violation the defendants, and the corporation in June 1946, entered pleas of *nolo contendere*. The defendant corporation was fined at that time in the amount of \$1250, and the defendants individually a nominal sum.

[*Change Pleas of Not Guilty to Guilty*]

The instant case proceeded to trial before a jury under the pleas of not guilty and evidence was adduced. Finally in the late stages of the trial the defendant, Gerbo, under advice of counsel, requested the court for a change of plea from not guilty to that of guilty. The court accepted the plea.

In addition, at that juncture, the Roma Macaroni Factory, a corporation, was permitted to change its plea of not guilty to guilty, to the several charges embraced in the said indictment. Upon motion of the defense counsel, the court entertained a motion for dismissal as to Albert Martinelli; there being no opposition on the part of the Government, Albert Martinelli was duly dismissed.

[*Plant in Filthy Condition*]

The crucial point, in the opinion of the court, is the date embraced in the indictment, to-wit, December 27, 1946. Notwithstanding a prior conviction in June 1946, and no doubt having received an admonition by the court that any further activities would result in more stringent penalties, the defendants saw fit to continue in the operations as they had been conducted prior to June, 1946, for it appears in the testimony elicited through Inspector McConnell that on December 27, 1946, or approximate thereto, and at the time of his inspection, the plant was in a filthy condition.

Evidences of vermin excrement, and the like were present and in addition the chemical analysis produced before the court, and testified to more recently by the Government expert, demonstrate that these filthy substances found their way into the finished product in such proportions as to justify any fact finding body in concluding that the plant had not been remedied as a result of or in the light of the prior conviction.

In short, these defendants, in the opinion of the court, saw fit to speculate to some degree: this is confirmed and reaffirmed by the testimony of Dr. Lowy, produced by the defendant in mitigation, who testified

that the condition on or about December 27, 1946, or at the time of the inspection of Mr. McConnell, demonstrated negligence.

He was honest with the court, and perforce he had to be honest, because inevitably that was the only conclusion to be reached.

[*Element of Intent Immaterial*]

(1) Counsel for the defendant has pointed out that the element of intent is not a prime requisite. It is not a matter of knowledge, or lack of knowledge. In examining the authorities the court has considered among others, *Triangle Candy Co. v. United States*, (C. C. A.-9, 1944), 144 F. (2d) 195, 155 A. L. R. 903, wherein it appeared that in the production of candy, unsanitary conditions prevailed; there were present in the candy rodent hairs, and the like. The court said that intent is no part of the crime with which defendants were charged. If they have introduced candy into interstate commerce, and if it is adulterated, they are guilty regardless of their intent or lack of knowledge as to adulteration.

Similarly, in *United States v. Swift & Co.*, (DC Ga., 1943), 53 F. Supp. 1018, it appeared that servants of the company had, in the manufacture of butter, permitted adulteration to creep into the product. The underlying philosophy, as I read the authorities, is the ultimate protection of the unwary purchaser and innocent consumer.

The very reason for the enactment in 1906 of the Food and Drugs Act and its avowed purpose, was that beneficent accomplishment. Title 21, U. S. C. A. § 1, *et seq.*

Congress saw fit to amend the act in 1938 and it is apparent that the criminal sanctions were increased. That is quite evident from a reading of the statute, wherein it appears, in part, that upon a second offense (Title 21 U. S. C. A. § 333), any person who violates any of the provisions of Section 331 of said Title shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such a person under that section, such person shall be subject to imprisonment for not more than three years or a fine of not more than \$10,000, or both such fine and imprisonment. Congress had in mind the imposition of that rather sev-



ere criminal penalty to avoid the consequences of that type of conduct which we have presently reviewed.

As I have indicated, and as the testimony developed, these defendants, at least the defendant Gerbo, who has entered a plea of guilty, in the main must be properly charged with the exercise of a studied indifference towards the consequences. We have this belated effort on his part to make whole the harm and injury that has been done. It is perfectly obvious, and I repeat myself, that between the first violation and December, 1946, very little if anything had been done. The evidence points unerringly to all these facts.

*[Filthy Food Substances Prohibited in Interstate Commerce]*

(2) In searching for authority with some reasonable analogy to the case at bar, I have considered *United States v. Lazere*, (DC Iowa, 1944), 56 F. Supp, 730, at pages 732, 733; and at 733, the Court used very significant language which I might paraphrase. It would not be good law, or good sense, to permit a person to put filthy food substances into interstate commerce, or to permit persons to prepare food for such purpose under unsanitary conditions. The Federal Food, Drug, and Cosmetic Act does not provide that parties shall avoid doing such things, if it is possible; it provides that it shall not be done at all. A party who cannot prepare food products under sanitary conditions must cease putting such products into interstate commerce.

*[Word "Filthy" has Usual and Ordinary Meaning]*

(3) In the *Lazere* case it appeared that in a number of sacks were found rodent excretion, pellets, and a number of sugar sacks had been gnawed; also the urine was pre-

sent, as in the case at bar. In addition, in that case the court defined "filthy" within the contemplation of the Act. Congress intended that the word "filthy" as used in the Act should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition.

*[Judgment of the Court]*

(4) To some extent, it has been a rather disagreeable experience for the court, and I know the jurors felt likewise in listening to the narrative testimony. The facts were revolting.

No doubt the premises were never equipped or were never suitable for the manufacture of food products. Dr. Lowy in his testimony again was extremely honest with the court, as he should have been, stating "Perhaps they had done the best they could."

We have the defendant Gerbo and the defendant corporation gambling and speculating with the hope, and no doubt expectation, that ultimately some court somewhere in the land would impose a modest fine and blessing, and they would go forth rejoicing. That is not the position of the court in this case.

Would the defendant Gerbo appear before the bar, and someone on behalf of the corporation?

As to the defendant Dominic Louis Gerbo, the court will refer the matter to the probation officer for a pre-sentence report. The defendant Dominic Louis Gerbo is remanded to custody.

With respect to the Roma Macaroni Factory, the judgment of the court is that the Roma Macaroni Factory, a corporation, pay a fine to the United States Government in the maximum amount of \$10,000.

## UNITED STATES v. JAMES JORDAN SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

United States Supreme Court. No. 121. October Term, 1947.

January 19, 1948. 332 U. S. 689.

Reversing 161 F. 2d 629. See page 334.

The defendant, a retail druggist, was prosecuted for taking sulfathiazole pills from a large container, placing them in a small container with only the word "sulfathiazole" on it, and selling them. The large container had labels which set out adequate directions for the use of the tablets and adequate warnings, but the small containers did not. Defendant had purchased the pills from a wholesaler in the same state, to whom the pills had theretofore been shipped in interstate commerce. A restrictive interpretation should not



be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question.

Sections 301 (k), 502 (f), Federal Food, Drug, and Cosmetic Act.

The scope of the offense which Congress defined in Section 301 (k) is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food and cosmetics.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The Federal Security Administrator is given broad enough discretion in the Act to enable him to perform his duties fairly without wasting his efforts on technical infractions of law.

Sections 306, 405, 503 (a), 603, Federal Food, Drug, and Cosmetic Act.

The chief purpose of forbidding, in Section 301 (k), the destruction of the label is to keep it intact for the information and protection of the consumer; and this purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred to a non-labeled container.

Sections 301 (k), 502 (f), Federal Food, Drug, and Cosmetic Act.

In any event, the words "while such article is held for sale after shipment in interstate commerce" accurately described the defendant's conduct; and the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

The meaning given to the literal language of Section 301 (k) is consistent with the purpose of the Act to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer.

Sections 201 (b), 301 (k), Federal Food, Drug, and Cosmetic Act.

Section 301 (k), as construed by the Supreme Court, is not beyond the authority granted Congress by the Constitution and is a valid exercise of the commerce power.

Section 301 (k), Federal Food, Drug, and Cosmetic Act.

Mr. Justice BLACK delivered the opinion of the Court: Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act of 1938. That section prohibits "the doing of any . . . act with respect to, a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."<sup>1</sup>

Section 502 (f) of the Act declares a drug "to be misbranded . . . unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users." The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole being "misbranded" while "held for sale after shipment in interstate commerce."

<sup>1</sup> "Sec. 301. The following acts and the causing thereof are hereby prohibited:

\* \* \*

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any

other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." 52 Stat. 1042, 21 U.S.C. § 331 (k).



[*The Facts*]

The facts alleged were these: A laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by Section 502 (f)(1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use.<sup>2</sup> Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled "sulfathiazole." They did not contain the statutorily required adequate directions for use or warnings of danger.

Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts.

[*Holding of Circuit Court of Appeals*]

The Circuit Court of Appeals reversed. 161 F. 2d 629. The court thought that as a result of respondent's action the sulfathiazole became "misbranded" within the meaning of the Federal Act, and that in its "broadest possible sense" the Act's language "may include what happened." However, it was also of the opinion that the Act ought not to be taken so broadly "but held to apply only to the holding for the first sale by the importer after interstate shipment." Thus the Circuit Court of Appeals interpreted the statutory language of Section 301 (k) "while such article is held for sale after shipment in interstate commerce" as though Congress had said "while such article is held for sale by a person who had himself received it by way of a shipment in interstate commerce." We granted certi-

orari to review this important question concerning the Act's coverage.

[*Reasoning of Circuit Court of Appeals*]

*First.* The narrow construction given Section 301 (k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language "while such article is held for sale after shipment in interstate commerce" should be given its literal meaning, the criminal provisions relied on would "apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of food, devices and cosmetics, for all these are equally covered by these provisions of the Act." The court emphasized that such consequences would result in far-reaching inroads upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission v. Bunte Bros.*, 312 U. S. 349. Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position the court cited *Labor Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 30, and *Schechter Poultry Corp. v. United States*, 295 U. S. 495.

A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or be-

<sup>2</sup> The following inscription appeared on the bottle labels as a compliance with Section 502 (f) (1) which requires directions as to use: "Caution.—To be used only by or on the prescription of a physician." This would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C. F. R. Cum. Supp., Section 2.106 (b) (3). The following appeared on the label of the bottles as a compliance with Section 502 (f) (2) which

requires warnings of danger: "Warning.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."



cause giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, see *Kraus & Bros., Inc. v. United States*, 327 U. S. 614, 621-622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States v. Raynor*, 302 U. S. 540, 552.

*[Application to Sales of Food, Drugs,  
Devices and Cosmetics]*

*Second.* Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to "similar retail sales of food, devices and cosmetics, for all of these," the court said, "are equally covered by the same provisions of the Act." And in this Court the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if Section 301 (k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion—broad enough undoubt-

edly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, Section 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately served. And the Administrator is given extensive authority under Sections 405, 503 and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of Section 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

*[Sale "After Shipment in Interstate  
Commerce"]*

*Third.* When we seek the meaning of Section 301 (k) from its language we find that the offense it creates and which is here charged requires the doing of some act with respect to a drug (1) which results in its being misbranded, (2) while the article is held for sale "after shipment in interstate commerce." Respondent has not seriously contended that the "misbranded" portion of Section 301 (k) is ambiguous. Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which Section 502 (f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a "misbranding," transferring the pills to non-branded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills he buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act.

Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of Section 301 (k) that the misbranding occur "while such article



is held for sale after shipment in interstate commerce." The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them nine months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of Section 301 (k).

[*Protection of the Consumer*]

*Fourth.* Given the meaning that we have found the literal language of Section 301 (k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States v. Dotterweich*, 320 U. S. 277, 282, after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301 (a) forbids the "introduction or delivery for introduction into interstate commerce" of misbranded or adulterated drugs; Section 301 (b) forbids the misbranding or adulteration of drugs while "in interstate commerce"; and Section 301 (c) prohibits the "receipt in interstate commerce" of any misbranded or adulterated drug, and "the delivery or proffered delivery thereof for pay or otherwise." But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) "while such article is held for sale after shipment in interstate commerce" apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into

the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows: "In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."<sup>3</sup> We hold that Section 301 (k) prohibits the misbranding charged in the information.

[*Applicability of the McDermott Case*]

*Fifth.* It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution and that it invades the power of the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott v. Wisconsin*, 228 U. S. 115. That Act did not contain Section 301 (k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained "unsold." The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case the labels involved were on the original containers; here the labels are required to be put on other than the original containers—the boxes to which the tablets were transferred. Also, in the *McDermott* case the possessor of the labeled cans held for sale had himself received them by way of an interstate sale and shipment; here the petitioner had received the sulfathiazole by way of an intrastate sale and shipment from a seller who had obtained them by way of an interstate shipment. These variants are not sufficient we think to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce. The reasons given for the *McDermott* holding therefore are equally applicable and persuasive here. And many cases decided since the *McDermott* decision

<sup>3</sup> H. Rep. 2139, 75th Cong., 3d Sess., 3.



lend support to the validity of Section 301 (k). See, e.g., *United States v. Walsh*, 331 U. S. 432; *Wickard v. Filburn*, 317 U. S. 111; *United States v. Wrightwood Dairy Co.*, 315 U. S. 110; *United States v. Darby*, 312 U. S. 100; see *United States v. Olsen*, 161 F. 2d 669.

*Reversed.*

### Concurring Opinion

MR. JUSTICE RUTLEDGE, concurring: This case has been presented as if the Federal Food, Drug, and Cosmetic Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

The trouble-making factor is not found in the statute's provisions relating specifically to drugs. Those provisions taken by themselves are clear and unequivocal in the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in Section 301 (k), they are interlaced with provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

If the statute as written required this, furnishing no substantial basis for differentiating such cases, the decision here would be more difficult than I conceive it to be. But I do not think the statute has laid the trap with which we are said to be faced. Only an oversimplified view of its terms and effects could produce that result.

The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. More is necessary for construction of the statute than looking merely to the terms of Sections 301 (k) and 502 (f).

It is true that Section 301 (k) deals indiscriminately with food, drugs, devices and cosmetics, on the surface of its terms alone. Hence it is said that the transfer of sulfathiazole, a highly dangerous drug, from a bulk container to a small box for retail sale, could not be "any other act" unless a similar transfer of candies, usually harmless, also would be "any other act." From this hypothesis it is then concluded that the phrase must be interpreted with reference to the particularities which precede it, namely, "alteration, mutilation, destruction, obliteration or removal" of any part of the label, and must be limited by those particularities.

That construction almost, if not quite, removes "any other act" from the section. And by doing so it goes far to emasculate the section's effective enforcement, especially in relation to drugs. Any dealer holding drugs for sale after shipment in interstate commerce could avoid the statute's effect simply by leaving the label intact, removing the contents from the bulk container, and selling them, however deadly, in broken parcels without label or warning.

I do not think Congress meant the phrase to be so disastrously limited. For the "doing of any other act with respect to a food, drug, device, or cosmetic" is prohibited by Section 301 (k) only "if such act . . . results in such article being misbranded." And the statute provides, not a single common definition of misbranding for foods, drugs and cosmetics, but separate and differing sections on misbranded foods, misbranded drugs and devices, and misbranded cosmetics. Sections 403, 502, 602.

The term "misbranded" as used in Section 301 (k) therefore is not one of uniform connotation. On the contrary, its meaning is variable in relation to the different commodities and the sections defining their misbranding. So also necessarily is the meaning of "any other act," which produces those misbranding consequences. Each of the three sections therefore must be taken into account in determining the meaning and intended scope of application for Section 301 (k) in relation to the specific type of commodity involved in the particular sale, if Congress' will is not to be overridden by broadside generalizations glossed upon the statute. As might have been expected, Congress did not lump food, drugs and cosmetics in one indis-



criminate hopper for the purpose of applying Section 301 (k), either in respect to misbranding or as to "any other act" which produces that consequence. Brief reference to the several misbranding sections incorporated by reference in Section 301 (k) substantiates this conclusion.

The three sections contain some common provisions.<sup>1</sup> But the fact that each section is also different from the other two in important respects indicates that each broad subdivision of the Act presents different problems of interpretation. Neither the misbranded foods section nor the misbranded cosmetics section contains any provision directly comparable to Section 502 (f), which the respondent here has violated. That section, however, is to be contrasted with Section 403 (k), one of the subsections dealing with misbranded foods. Comparison of the two provisions indicates that the doing of a particular act with respect to a drug may result in misbranding, whereas the same method of selling food would be proper.

Section 502 (f) provides that a drug shall be deemed to be misbranded:

"Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."

This provision, dealing with directions for use and warnings against improper use, in terms is designed "for the protection of users." To be effective, this protection requires regulation of the label which the container bears when the drug reaches the ultimate consumer.<sup>2</sup> The legislative history leaves no doubt that the draftsmen and sponsors realized the importance of having dangerous drugs properly labeled at the time of use, not just at the time of sale.<sup>3</sup> The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Adminis-

trator to make exemptions only when compliance with clause (1) "is not necessary for the protection of public health."

Section 403 (k), which contains the principal basis for "making every retail grocer a criminal," is very different. By its terms food is deemed to be misbranded:

"If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream."

The section, in contrast to Section 502 (f)'s coverage of drugs, applies not to all foods shipped interstate, but only to the restricted classes containing artificial flavoring, or coloring, or chemical preservatives. The labeling requirement is much simpler. And the proviso confers a much broader power of exemption upon the Administrator than does the proviso of Section 502 (f). Under the latter he is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protection of the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

Under Section 403 (k), however, in dealing with foods the Administrator can dispense with labels much more broadly. In terms the criterion for his action becomes "the extent to which compliance . . . is impracticable" rather than, as under Section 502 (f), "where any requirement of clause 1 [adequate directions for use] . . . is not necessary for the protection of the public health." Practical considerations affecting the burden of compliance by manufacturers and retailers, irrelevant under Section 502 (f), become controlling under Section 403 (k). Thus under the statute's intent a much more rigid and invariable compliance with the labeling requirements for drugs is contemplated than for those with foods, apart from its greatly narrower coverage

<sup>1</sup> *E.g.*, Sections 403 (a), 502 (a) and 602 (a) are in identical language.

<sup>2</sup> See S. Rep. No. 361, 74th Cong., 1st Sess., 19.

<sup>3</sup> See H. R. Rep. No. 2139, 75th Cong., 3d Sess. 8.



of the latter. And the difficulty of compliance with those requirements for such articles as candies explains the difference in the two provisos.<sup>4</sup>

These differences, and particularly the differences in the provisos, have a direct and an intended relation to the problem of enforcement. The labeling requirements for foods are given much narrower and more selective scope for application than those for drugs, a difference magnified by the conversely differing room allowed for exemptions. What is perhaps equally important, the provisos are relevant to enforcement beyond specific action taken by the Administrator to create exemptions.

His duty under both sections is cast in mandatory terms. Whether or not he can be forced by mandamus to act in certain situations, his failure to act in some would seem to be clearly in violation of his duty. Obviously there must be many more instances where compliance with the labeling requirements for foods will be "impracticable" than where compliance with the very different requirements for drugs will not be "necessary for the protection of the public health." That difference is obviously important for enforcement, particularly by criminal prosecution. I think it is one which courts are entitled to take into account when called upon to punish violations. The authors of the legislation recognized expressly that "technical, innocent violations . . . will frequently arise." S. Rep. No. 152, 75th Cong., 1st Sess. 4. In other words, there will be conduct which may be prohibited by the Act's literal wording, but which nevertheless should be immune to prosecution.

When that situation arises, as it well may with reference to foods, by virtue of the Administrator's failure to discharge his duty to create exemptions before the dealer's questioned action takes place, that failure in my judgment is a matter for the court's consideration in determining whether prosecution should proceed. And whenever it is made to appear that the violation is a "technical, innocent" one, an act

for which the Administrator should have made exemption as required by Section 403 (k), the prosecution should be stopped. This Court has not hesitated to direct retroactive administrative determination of private rights when that unusual course seemed to it the appropriate solution for their determination. *Addison v. Holly Hill Fruit Products*, 322 U. S. 607. If that is permissible in civil litigation, there is much greater reason for taking the analogous step of taking into account in a criminal prosecution an administrative officer's failure to take commanded action which, if taken, would have made prosecution impossible.

It is clear therefore that the corner grocer occupies no such position of jeopardy under this legislation as the druggist, and that the meaning of Section 301 (k) is not identical for the two, either as to what amounts to misbranding or as to what is "the doing of any . . . act" creating that result. The supposed dilemma is false. Congress clearly had power to impose the drug restrictions, they are clearly applicable to this case, the decision does not rule the corner grocer selling candy, and the judgment should be reversed. I therefore join in the Court's judgment and opinion to that effect.

#### Dissenting Opinion

MR. JUSTICE FRANKFURTER, dissenting: If it takes nine pages to determine the scope of a statute, its meaning can hardly be so clear that he who runs may read, or that even he who reads may read. Generalities regarding the effect to be given to the "clear meaning" of a statute do not make the meaning of a particular statute "clear." The Court's opinion barely faces what, on the balance of considerations, seems to me to be the controlling difficulty in its rendering of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1042; 21 U. S. C. Section 331 (k). That section no doubt relates to articles "held for sale after shipment in interstate commerce and results in such article being

<sup>4</sup> "The proviso of this paragraph likewise requires the establishment of regulations exempting packages of assorted foods from the naming of ingredients or from their appearance in the order of predominance by weight where, under good manufacturing practice, label declaration of such information is impracticable. This provision will be particularly applicable, for example, to assorted confections, which under normal manufacturing practices may vary from

package to package not only with respect to identity of ingredients but also to regard to the relative proportions of such ingredients as are common to all packages." S. Rep. No. 493, 73d Cong., 2d Sess. (1934). The proviso discussed is in Section 403 (i), not in Section 403 (k); but the discussion brings out the sort of considerations which require exemption when compliance is impracticable.



misbranded." But an article is "misbranded" only if there is "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic." Here there was no "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. The decisive question is whether taking a unit from a container and putting it in a bag, whether it be food, drug or cosmetic, is doing "any other act" in the context in which that phrase is used in the setting of the Federal Food, Drug, and Cosmetic Act and particularly of Section 301 (k).<sup>1</sup>

As bearing upon the appropriate answer to this question, it cannot be that a transfer from a jar, the bulk container, to a small paper bag, without transferring the label of the jar to the paper bag, is "any other act" when applied to a drug, but not "any other act" when applied to candies or cosmetics. Before we reach the possible discretion that may be exercised in prosecuting a certain conduct, it must be determined whether there is anything to prosecute. Therefore, it cannot be put off to some other day to determine whether "any other act" in Section 301 (k) applies to the ordinary retail sale of candies or cosmetics in every drug store or grocery throughout the land, and so places every corner grocery and drug store under the hazard that the Administrator may report such conduct for prosecution. That question is now here. It is part of this very case, for the simple reason that the prohibited conduct of Section 301 (k) applies with equal force, through the same phrase, to food, drugs and cosmetics insofar as they are required to be labeled. See Sections 403, 502, and 602 of the Act.

It is this inescapable conjunction of food,

drugs and cosmetics in the prohibition of Section 301 (k) that calls for a consideration of the phrase "or the doing of any other act," in the context of the rest of the sentence and with due regard for the important fact that the States are also deeply concerned with the protection of the health and welfare of their citizens on transactions peculiarly within local enforcing powers. So considered, "the doing of any other act" should be read with the meaning which radiates to that loose phrase from the particularities that precede it, namely "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. To disregard all these considerations and then find "a clear meaning" is to reach a sum by omitting figures to be added. There is nothing in the legislative history of the Act, including the excerpt from the Committee Report on which reliance is placed, to give the slightest basis for inferring that Congress contemplated what the Court now finds in the statute. The statute in its entirety was of course intended to protect the ultimate consumer. This is as true in regard to the requirements pertaining to drugs as of those pertaining to food. As to the reach of the statute—the means by which its ultimate purpose is to be achieved—the legislative history sheds precisely the same light on the provisions pertaining to food as on the provisions pertaining to drugs. If differentiations are to be made in the enforcement of the Act and in the meaning which the ordinary person is to derive from the Act, such differentiations are interpolations of construction. They are not expressions by Congress.

In the light of this approach to the problem of construction presented by this Act, I would affirm the judgment below.

MR. JUSTICE REED and MR. JUSTICE JACKSON join in this dissent.

<sup>1</sup> "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device,

or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."



**UNITED STATES v. CRESCENT- KELVAN COMPANY, AN  
ASSOCIATION, AND JEREMIAH T. ROACH AND  
GEORGE DUKE LAMBERT, INDIVIDUALS**

United States Circuit Court of Appeals for the Third Circuit. No. 9350.  
January 26, 1948. 164 F. 2d 582.

The defendants were convicted of having shipped in interstate commerce a drug which was adulterated in that it contained a coal-tar color which had not been certified for use, and a drug which was misbranded in that the label failed to bear the common or usual name of each active ingredient. A Food and Drug Administration inspector had inspected the defendants' premises and shipping records, and had taken a sample. It was held that leave and permission to enter were tacitly granted by the individual defendants, that under the statute the inspector had the right to examine the package containing the prohibited coal-tar color, but that even if the inspector had no express right to take a sample, the individual defendants acquiesced.

Sections 301 (a), 501 (a), 502 (e), 704, Federal Food, Drug, and  
Cosmetic Act.

In accord with the canons of statutory construction, it may be that inspection of a "factory" includes the inspection of everything to be found therein relating to the business of the factory, including the factory's shipping records.

Sections 703, 704, Federal Food, Drug, and Cosmetic Act.

Section 704 is constitutional; its provisions are bottomed upon the police power of the United States as exercised under the Commerce Clause of the Constitution for the protection of the public health.

Section 704, Federal Food, Drug, and Cosmetic Act.

Congress intended that drugs should be labeled with the name by which they are known to the community at large; Congress did not intend to limit the designation of "common or usual name" by some other phrase as "known to physicians or to druggists."

Section 502 (e), Federal Food, Drug, and Cosmetic Act.

It is not true that if the drug involved was designated on the bottle's label by a name employed in the National Formulary, the defendants were relieved of liability. The employment of the name by the Formulary must be treated as evidence to be weighed by the jury, with all the other evidence, as to what is the common or usual name of the drug. The charge of the court below in that respect was insufficient.

Sections 201 (g), 201 (j), 502 (e), Federal Food, Drug, and Cosmetic  
Act.

The trial court should have charged the jury that if it believed the evidence of the responsibility of the individual defendants for the acts of the company to be worthy of credence, then it could find that the individual defendants were responsible for the company's misconduct.

Section 301 (a), Federal Food, Drug and Cosmetic Act.

Viewed as a whole, the charge respecting the necessity of a finding by the jury that the proof offered by the United States was sufficient to prove the defendants' guilt beyond a reasonable doubt was not clear, and constituted error.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.



Rule 30 of the Federal Rules of Criminal Procedure provides that "The Court shall inform counsel of its proposed action upon the requests [for charge] prior to their arguments to the jury" and should be observed.

Section 301 (a), Federal Food, Drug, and Cosmetic Act.

Where there are two counts, the trial court should charge the jury that it should find the respective defendants guilty or not guilty on each count.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

Roland J. Christy, Philadelphia, Penn., for appellant.

Edward A. Kallick, Philadelphia, Penn. (Gerald A. Gleeson, U.S. Atty., of Philadelphia, Pa., Theron L. Caudle, Asst. Atty. Gen., Vincent A. Kleinfeld and John T. Grigsby, Attys., Department of Justice, both of Washington, D.C., on the brief), for appellee.

Before BIGGS, ALBERT LEE STEPHENS and MARIS, Circuit Judges.

### Opinion of the Court

BIGGS, Circuit Judge: The information in the case at bar charges Crescent-Kelvan Company and the individual defendants in two separate counts with violations of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, Section 1 *et seq.*, 52 Stat. 1040 (1938), 21 U. S. C. A. § 301 *et seq.* (Supp. 1946).

#### [The Counts]

The first count charges that the defendants caused to be shipped in interstate commerce a drug, known by the trade name of "Methosol," adulterated within the purview of Section 501 (a) (4) of the Act, 21 U. S. C. A. § 351 (a) (4) (Supp. 1946), in that it contained, for purpose of coloring only, a coal-tar color, "Butter Yellow," actually dimethylamino-azobenzene, which had not been certified for use in accordance with the regulations<sup>1</sup> promulgated under Section 504 of the Act, 21 U. S. C. A. § 354 (Supp. 1946). The defendants do not contend that the drug was not within the purview and prohibition of the statute. Their defenses lie on other grounds which will be dealt with hereinafter.

The second count charges a violation of Section 502 (e) of the Act, 21 U. S. C. A. § 352 (e) (Supp. 1946), in that the defendants caused to be shipped in interstate commerce certain capsules in a bottle labeled in pertinent part as follows: "1000 (Capsules) BENZ-CAL-CIN, Trade Mark, Chemical Combination Benzoinated-Phenyl Cinchoninic Acid and Calcium. . . . Each capsule represents Phenyl cinchoninic acid approximately two grains." The gravamen of the charge in the count is misbranding in that the drug, "Benz-Cal-Cin," a fabrication of two or more ingredients, was not desig-

nated solely by a name recognized in an official compendium, the label on the bottle failing to bear the common or used name of each active ingredient, viz., free cinchophen and cinchophen in chemical combination. The defendants contend that the name on the label, "phenylcinchoninic acid," was a common or usual name of the drug.

#### [Status of the Crescent-Kelvan Company]

The facts as shown by the evidence are as follows: While the precise status of Crescent-Kelvan Company cannot be ascertained from the record, it is described in the information as "an association existing as a business trust under the laws of the Commonwealth of Pennsylvania . . .". The learned trial judge in his charge told the jury that it was an "association," and that an association "simply means that they operate as a business trust, which they can properly do under the laws of the Commonwealth of Pennsylvania." Exhibit G-7, a bill of the Crescent-Kelvan Company, states that it is "A Trust," and that the defendant Roach is its president and that the defendant Lambert is its secretary-treasurer while M. W. Lambert is shown as "Trustee." It was stipulated by counsel that if the Prothonotary of the Court of Common Pleas, Philadelphia County, were to testify he would produce a certificate, June Term, 1941, C. P. No. 3, 475, signed by Roland J. Christy, dated August 27, 1941, registering under the fictitious name, Crescent-Kelvan Company, which was characterized as "Chemists to the Medical Professions . . ." and filed by the defendant Lambert as treasurer. We think it may be assumed in the light of the foregoing that Crescent-Kelvan Company was regis-

<sup>1</sup> See 21 C. F. R. Cum. Supp., 135.1-15 (1944).



tered under the Pennsylvania Fictitious Names Act, 54 PS Pa. § 21 (1930), and that it is a "Massachusetts trust" of the sort referred to by the Supreme Court of Pennsylvania in *Pennsylvania Company, etc., v. Wallace*, 346 Pa. 532, 31 A. 2d 71. In any event it is clear that the defendant Roach purported to act as the president of Crescent-Kelvan Company and that the defendant Lambert purported to act as its secretary-treasurer; that the individual defendants were in charge of the books, records and premises of Crescent-Kelvan Company and that their acts on behalf of it are sufficient to bind the "Trust."

[*Testimony of the Inspector*]

In March, 1944, an inspector of the Philadelphia station of the Food and Drug Administration came to the plant of Crescent-Kelvan Company where the individual defendants were in charge, and inspected the premises. Wagner, the inspector, testified that the inspection was made to ascertain the use by Crescent-Kelvan Company of coal-tar colors in drug products and that he found in the plant a package labeled "D & O,<sup>2</sup> 4 oz. color, No. 305, for technical use only."; that he was informed that this coal-tar color was used in the defendants' product "Methosol"; that he took a sample therefrom, without objection from the individual defendants, offering to pay for it, an offer which was refused.

Wagner further testified that thereafter he inspected the shipping records of Crescent-Kelvan Company and found that Methosol had been shipped by it to a physician in Maryland, and that Benz-Cal-Cin capsules had been shipped to another doctor in the same state. The two doctors testified that they had received respectively from Crescent-Kelvan Company by parcel post Methosol and Benz-Cal-Cin capsules. There was further testimony by an agent of the Administration that samples of these drugs had been procured from the physicians. Chemists employed by the Administration testified that the Methosol thus procured contained the prohibited coal-tar coloring Butter Yellow and that the Benz-Cal-Cin capsules contained free chinchofen and cinchophen in chemical combination.

[*Jury Verdict*]

The jury found all defendants guilty on the counts of the information and the court entered judgments of sentence imposing a fine on Crescent-Kelvan Company and sentencing the individual defendants to both fine and imprisonment, the sentences of imprisonment, however, being suspended and the individual defendants being placed upon probation. All the defendants have appealed.

[*Alleged Grounds for Reversal*]

Substantially all of the testimony offered by the United States<sup>3</sup> was subject to repeated objections by the defendants. This brings us immediately to a discussion of the first point raised by them as grounds for reversal. The inspector of the Food and Drug Administration entered the premises of Crescent-Kelvan Company without a search warrant. The defendants assert that they were deprived of the rights guaranteed to them by the Fourth Amendment of the Federal Constitution and that their effects were subjected to unreasonable search and seizure because the inspector made the inspection without a search warrant, because he obtained a sample of the prohibited coal-tar color and, above all, because he inspected the shipping records from which the names of the Maryland doctors were obtained. This inspection of course led ultimately to samples of Methosol and Benz-Cal-Cin capsules being introduced into evidence at the trial.

[*Provisions of Section 704*]

Passing by the question as to whether or not the guarantees of the Fourth Amendment may be invoked by a "Trust" such as that at bar, a question which we need not answer, we find it unnecessary to deal with the defendants' contentions at length for the following reasons. Section 704 of the Act, 21 U. S. C. A. § 374 (Supp. 1946), provides that officers designated by the Administrator, after first making a request and obtaining permission of the owner, or custodian are authorized to enter, at reasonable times, any factory in which drugs are manufactured, processed, packed or held, for introduction to interstate commerce; and to inspect, at reasonable times, such factory and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

<sup>2</sup> The product was distributed by Dodge & Olcott of New York City.

<sup>3</sup> None was offered on behalf of the defendants.



It is not contended that the inspector came upon the premises at an unreasonable time or forced his way into Crescent-Kelvan Company's plant. It is clear from the testimony that whether the inspector expressly requested leave to enter and received such permission from the individual defendants who were in fact in charge of the premises, leave and permission to enter were tacitly granted to the inspector by the individual defendants. Under the statute the inspector had the right to examine the package containing the prohibited coal-tar color, Butter Yellow. But even if the inspector had no express right under the statute to take a sample of the coal-tar color, the individual defendants consented and acquiesced in that taking. It is manifest also that whether or not the statute conferred upon the inspector the right to examine the shipping records of Crescent-Kelvan Company, permission to make such an inspection was implicitly granted to them by the individual defendants then present<sup>4</sup> who had the right to bind the "Trust." We find it unnecessary, therefore, to embark upon a discussion of the authority granted to the inspector by the statute.

[Section 704 Is Constitutional]

We entertain no doubt that Section 704 is constitutional. Its provisions are bottomed upon the police power of the United States as exercised under the Commerce Clause of the Constitution for the protection of the public health.<sup>5</sup> See *McDermott v. Wisconsin*, 228 U. S. 115, 128; *Hipolite Egg Co. v. United States*, 220 U. S. 45, 47, and *Seven Cases v. United States*, 239 U. S. 510. No constitutional right is violated by a statute, an ordinance or a regulation providing for the inspection of places of business, dealing with drugs or foods during business hours. See *Keiper v. City of Louisville*, 152 Ky. 691, 154 S. W. 18, *State ex rel. Melton v. Nolan*, 161 Tenn. 293, 30 S. W. 2d 601,

and the authorities collected in 47 Am. Jur. pp. 508-510. By its express terms Section 704 provides for inspection of factory premises only after first obtaining permission from the custodian thereof. The section is patterned on Section 3601 of the Internal Revenue Code and the authority exercised under that statute has never been regarded as violative of the guarantees of the Fourth Amendment. See *Cooper v. United States*, 3 Cir. 299 F. 483; *United States v. Vlahos*, 19 F. Supp. 166 (Ore); *In re Meador*, 16 F. Cas. No. 9375. See also *United States v. Barnes*, 222 U. S. 513, and *McDermott v. Wisconsin*, 228 U. S. 115. The inspector in examining the premises and the shipping records of Crescent-Kelvan Company did no act which constituted a violation of the Fourth Amendment.

[Question of Sufficiency of the Charge]

Other grounds asserted by the defendants, however, require reversal of the judgments of conviction and a new trial. These grounds go to the sufficiency of the charge. This subject requires a brief discussion of the offense laid in the second count of the information and of the terms of the statute alleged to have been violated.<sup>6</sup> As we already stated the second count of the information is based on an alleged violation of Section 502 (e) of the Act which provides that a drug shall be deemed to be misbranded "If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears . . . in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient . . .". The drug contained in the Benz-Cal-Cin capsules was not designated "solely" by a name recognized in an official compendium since it was described by the name "Benz-Cal-Cin," a trade name, and also was designated as a chemical combination, "Benzoinated-Phenyl Cinchoninic Acid and Calcium." The evi-

<sup>4</sup> Comparing the provisions of Section 704 of the Act, 21 U. S. C. A. § 374 (Supp. 1946), with those of section 703, 21 U. S. C. A. § 373 (Supp. 1946), relating to the inspection of drugs in the possession of carriers engaged in interstate commerce, it should be noted that the right to inspect shipping records is expressly conferred upon officers of the Administration. Since the right to inspect shipping records is not expressly conferred upon inspectors making inspections of factories, it may be argued that an inspection of a factory under the latter section would not include an inspection of the factory's shipping records. On the other side, it may be argued that inspection of a "factory" includes

the inspection of everything to be found therein relating to the business of the factory. The latter view seems to us to be more in accord with the canons of statutory construction but it is unnecessary to decide this question in the case at bar.

<sup>5</sup> See Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 26, and H. R. Rep. No. 2139, 75th Cong., 3rd Sess., pp. 2, 12.

<sup>6</sup> No comment respecting the sufficiency of the first count of the information or the charge of the court below thereon is necessary for reasons already apparent.



dence presented shows that Benz-Cal-Cin was fabricated from two or more ingredients. Therefore, under the terms of the statute the active ingredient or ingredients should have been designated by their respective "common or usual" name. The evidence offered will support the view that the active ingredient in the capsules was cinchophen or, as it is sometimes called, phenylcinchoninic acid.<sup>7</sup> The question, therefore, was whether or not the label on the bottle containing the capsules designated the active ingredient by its common or usual name.

[Definitions]

What did Congress mean when it made use of the phrase "common or usual name?" The adjective "common" has a multiplicity of definitions, but the first and the usual definition is "Belonging or pertaining to the community at large . . . habitual or notorious . . .".<sup>8</sup> The adjective "usual" is ordinarily deemed to be synonymous with the adjective "common." We think, therefore, that Congress intended that drugs should be labeled with the name by which they are known to the community at large. Cinchophen is a powerful drug which has been used as a diuretic in gout and to relieve acute articular rheumatism.<sup>9</sup> Though we may assume that it cannot be procured without a prescription and that therefore it would come into the hands of a member of the public only when prescribed by a physician, none the less we are of the opinion that Congress did not intend to limit the designation of "common or usual name" by some such further phrase as "known to physicians or to druggists." To hold to the contrary would be to amend the statute by judicial interpretation.

<sup>7</sup> Cinchophen or phenylcinchoninic acid apparently was the only active ingredient. Cinchophen or phenylcinchoninic acid are the same drug, sometimes also called phenyl-quinoline-carboxylic acid. See the National Formulary, 7th Edition, 1942, published by the American Pharmaceutical Association, at p. 95.

<sup>8</sup> See Webster's New International Dictionary, 2d Edition.

<sup>9</sup> See the American Illustrated Medical Dictionary, Dorland, 19th Edition. The drug has since been removed from some formularies by reason of its propensity to cause acute jaundice.

<sup>10</sup> Which provides: "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 52 Stat. 1042 (1938), 21 U. S. C. A. § 331 (Supp. 1946).

[Usual Name of Drug Question for Jury]

Evidence was offered that the common or usual name of the active ingredients in the Benz-Cal-Cin capsules introduced by the defendants in interstate commerce was "cinchophen." The defendants, relying upon the provisions of Section 301 (a) of the Act, 21 U. S. C. A. § 331 (a) (Supp. 1946),<sup>10</sup> and specifically on those of Section 201 (g) and (j) of the Act, 21 U. S. C. A. § 321 (g) and (j) (Supp. 1946),<sup>11</sup> seem to take the position that if the drug contained in the Benz-Cal-Cin capsules was designated on the bottle's label by a name employed in the official National Formulary,<sup>12</sup> they were relieved from the criminal sanctions of the Act. In this they are in error. While The National Formulary refers to the drug under consideration as "Cinchophen," "Phenylcinchoninic Acid" and "Phenyl-Quinoline-Carboxylic Acid,"<sup>13</sup> the employment of these names by The National Formulary must be treated only as evidence to be weighed by the jury, in addition to all the other evidence presented, as to what is the common or usual name of the drug. In other words, the question for the jury on this phase of the case is whether the descriptive term *phenyl cinchoninic acid* is the common or usual name of the drug, or whether the word *cinchophen* is its common or usual name as contended by the United States.

The charge of the court below was insufficient in that it did not set out clearly and adequately this issue of fact. This was the vital issue presented by count 2 of the information and the evidence adduced thereunder. The failure of the trial court to charge the jury adequately on this point was error which requires reversal of the judgment of conviction on the second count.

<sup>11</sup> As follows: "(g) The term 'drug' means (1) articles recognized in the . . . official National Formulary . . . ; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . ." [and] "(j) The term 'official compendium' means the . . . official National Formulary . . .".

<sup>12</sup> The official "The National Formulary", 7th Edition, 1942, published by The American Pharmaceutical Association, p. 95, was introduced into evidence.

<sup>13</sup> The word "Cinchophen", when first employed in the nomenclature of The National Formulary, is in **boldface** type. The other names in the nomenclature are not. Throughout the article respecting the drug in The National Formulary the reference is usually to "Cinchophen".



*[Instructions of Trial Judge]*

Referring now to the charge generally, we find further error. The learned trial judge stated: "Jeremiah T. Roach and George Duke Lambert [the individual defendants] are responsible as individuals under the law, and under this information, as it is drawn, for the acts committed by the company contrary to the Federal law." As we have said the status of the defendant, Crescent-Kelvan Company, is not entirely clear, but putting to one side any question as to the precise nature of the association or trust it is clear that the court below charged that the individual defendants were responsible for the acts committed by Crescent-Kelvan Company. But even if there be evidence to support a conclusion by the jury that the individual defendants were responsible "for the acts committed by the Company" the charge is erroneous none the less. The learned District Judge in fact charged the jury that the individual defendants *were* responsible for the acts committed by Crescent-Kelvan Company. In effect he gave binding instructions in this respect. The trial court should have charged the jury in the usual way that if they believed the evidence of the responsibility of the individual defendants for the acts of Crescent-Kelvan Company to be worthy of credence, then they could find that the individual defendants were responsible for Crescent-Kelvan Company's misconduct. This portion of the charge was erroneous and worked prejudice to the individual defendants and to Crescent-Kelvan Company as well.

The trial court also, quite inadvertently we know, fairly consistently throughout its charge stated that the guilt of the defendants was to be proved, to quote a typical instance, "by proving by preponderance of the evidence their wrongdoing." This misstatement was called to the court's attention by the counsel for the defendants at the close of the charge and the court then charged that the United States "has the burden throughout the trial of establishing, beyond a reasonable doubt, every fact essential to the conviction of the defendants . . .". Thereafter, counsel for the United States suggested to the court that it might explain to the jury "the question of reasonable doubt, eliminate the words 'preponderance of the evidence' and stick to 'reasonable doubt'." The court said to the jury

in response to this suggestion, "The question of reasonable doubt is the question that you are to determine. If you are satisfied beyond a reasonable doubt that in the first count of the information that there was an adulteration, that is sufficient; if you are satisfied on the second count beyond a reasonable doubt that this was misbranded, that is sufficient. Does that answer your question?—*that is the preponderance of the evidence.*"<sup>14</sup>

*[Charge Not Clear]*

We are of the opinion that viewed as a whole the charge respecting the necessity of the jury finding that the proof offered by the United States was sufficient to prove the defendants' guilt beyond reasonable doubt, was not clear. The learned trial judge had probably cured the original defects of the charge in this respect until he added the final clause italicized above, "that is the preponderance of the evidence." This so confused what he had stated previously that, in our opinion, the jury may well have been misled. Under all the circumstances the charge must be deemed to have been erroneous in this respect. Compare the circumstances of *Pomerantz v. United States*, 3 Cir., 51 F. 2d 911, and of *Thompson v. United States*, 3 Cir., 283 F. 895. The defendants in a criminal case are entitled to a clear and unequivocal charge by the court that the guilt of the defendants must be proved beyond a reasonable doubt.

In this connection we deem it desirable to call attention to Rule 30 of the Federal Rules of Criminal Procedure, 18 U. S. C. A., foll. Section 687 (Supp. 1946), which provides *inter alia*, that, "The court shall inform counsel of its proposed action upon the requests [for charge] prior to their arguments to the jury . . .". We cannot say that the error in the charge respecting reasonable doubt would not have occurred had the trial court followed the provisions of Rule 30 and, therefore, we may not say that the defendants were prejudiced by the failure of the trial court to observe the rule. It is possible and even probable, however, that had the provisions of Rule 30 been observed, the court below might not have fallen into error in its charge respecting reasonable doubt. The provisions of the Criminal Rules should be observed.

*[Separate Verdicts Not Rendered]*

Another matter respecting the charge re-

<sup>14</sup> Italics added.



mains for consideration. As we have stated, there are three defendants and there are two counts in the indictment. The jury did not render separate verdicts as to the individual defendants in respect to their guilt on *each* of the two counts. The court did not charge the jury that they should find the respective defendants guilty or not guilty on *each* count of the information. That the jury did not render separate verdicts as to the guilt or innocence of the defendants on each of the two counts is demonstrated by the transcript of what took place in the court room upon the return of the jury with the verdicts. In other words, the jury found all of the defendants guilty without differentiation as to each count. The court then sentenced the defendants, as demonstrated by the respective judgments of conviction and the commitments, without differentiation as to the counts, imposing the respective sentences set out at an earlier point in this opinion.

The error of the course pursued is, we think, immediately demonstrable by assuming a case in which the appellate tribunal sets aside a judgment of conviction or directs a verdict of acquittal on one of two counts of an indictment or information, the defendant having been found guilty on both counts and sentence having been imposed without regard to the separate counts. Under such circumstances how can the single sentence run against the defendant? He re-

ceived one sentence on two counts. But the appellate tribunal found that there was enough evidence to support a conviction based on one count and that the trial court had properly charged the jury as to the law respecting that count; whereas, it found that though the evidence was sufficient to support the offense laid in the other count, the trial court had not properly charged the jury respecting the law applicable to that count. Under such circumstances a new trial would be necessary for upon remand the court below could not distinguish between the general verdict of the jury applicable to both counts. To state the matter in other words we say that where there are separate counts in an indictment or information, there must be separate verdicts by the jury, under proper instructions from the court, as to the guilt or innocence of each defendant on each count if a judgment of conviction is to stand where there is error in the record affecting one or more of the counts. The failure of differentiation in the case at bar is not important since the errors of the charge require reversal as to both counts in any event. The practice of separate verdicts on separate counts should be adhered to by the district courts of this circuit where more than one count is contained in an indictment or information.

The judgments of conviction will be reversed.

---

**UNITED STATES v. DINSHAH P. GHADIALI AND  
DINSHAH SPECTRO-CHROME INSTITUTE**

United States Circuit Court of Appeals for the Third Circuit. No. 9352.

Filed February 9, 1948. 165 F. 2d 957.

Certiorari denied, 334 U. S. 821 (1948).

The defendants were convicted of having introduced into interstate commerce Spectro-Chrome devices which were misbranded because of therapeutic claims made in accompanying literature. The Government presented a large amount of evidence which, if believed, was amply sufficient to support a finding by the jury that the labeling of the devices was false and misleading in that they did not have the therapeutic value claimed for them.

Sections 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The Circuit Court of Appeals' careful consideration of the case left the court completely satisfied that the defendants had had a fair trial.

Sections 301 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

Dinshah P. Ghadiali, Malaga, N. J., for appellant.

Grover C. Richman, Assistant U. S. Attorney, Camden, N.J., for appellee.

Before MARIS, McLAUGHLIN, and KALODNER, Circuit Judges.



## [Facts]

PER CURIAM: The defendants have appealed from their conviction in the district court for the district of New Jersey upon twelve counts of an indictment charging them with introducing into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. chap. 9), certain devices known as Spectro-Chromes intended for use in the cure, mitigation, treatment and prevention of disease

in man, which were misbranded. The devices in question consisted of a cabinet equipped with a 1,000 watt electric light bulb, an electric fan and water container for cooling purposes, two glass condenser lenses to focus the rays from the electric light bulb and five ordinary glass slides, each of a different color. Attached to the devices were plate labels bearing, in part, the following:

“SPECTRO-CHROME METRY  
MEASUREMENT AND RESTORATION OF THE HUMAN  
RADIO-ACTIVE AND RADIO-EMANATIVE EQUILIBRIUM  
(NORMALATION OF IMBALANCE)

BY

ATTUNED COLOR WAVES  
THE SCIENCE OF AUTOMATIC PRECISION  
NO DIAGNOSIS—NO DRUGS—NO MANIPULATION—NO SURGERY  
ORIGINATED, DEVELOPED, APPLIED, COPYRIGHTED 1920 BY

COLONEL DINSHAH P. GHADIALI, M.S.C.,  
M.D., M.E., D.C., PH.D., LL.D., N. D., D.OPT., D.F.S., D.H.T., D.M.T., D.S.T., Etc.  
METAPHYSICIAN AND PSYCHOLOGIST”

## [Labeling]

The devices were accompanied by various pieces of printed matter, two of them being entitled in part “Spectro-Chrome Home Guide” and “Favorscope,” which related to the devices and contained statements relative to their therapeutic value in the cure, mitigation, treatment or prevention of disease, and directions for their use. The directions called for doing what the defendants call “irradiating” the body of the patient with what the defendants describe as “attuned color waves” projected by the device through the colored glass slides. The particular slide or combination of slides required to produce the exact color said to be needed to treat a given disorder was specified in the “Spectro-Chrome Home Guide.” The patient was advised to adhere to a designated diet. He was directed to subject himself to “irradiation” while facing south or lying in a north and south position with his head to the north. The “tonations” from the Spectro-Chrome were to be taken at times specified by the defendants in the “favorscope” which accompanied the device and which, they alleged, was compiled on the basis of solar, lunar and terrestrial radiant, gravitational influence.

## [Law]

The government presented a large amount

of evidence which, if believed, was amply sufficient to support a finding by the jury that the labeling of the defendants’ Spectro-Chrome device was false and misleading within the meaning of Section 502 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. § 352 (a)) in that the device did not have the therapeutic value which the labeling claimed for it. The jury, evidently believing the government’s evidence, found the defendants guilty of violating the act. The defendants upon the present appeal have presented eleven points which they assert require the reversal of the judgment of the district court. We have examined with care each of the points raised by the defendants and we find each to be wholly lacking in merit. It would serve no useful purpose to discuss them in detail. Suffice it to say that our consideration of the case has left us completely satisfied that the defendants had a fair trial. Indeed the trial judge, if anything, leaned over backward to afford them the fullest opportunity to establish their defense and he submitted their case to the jury in a charge to which no objection was or fairly could be made.

The judgment of the district court will be affirmed.



UNITED STATES v. BESS J. LEVINE, AN INDIVIDUAL  
TRADING AS MIRACLE FOOD COMPANY

United States District Court for the Eastern District of Pennsylvania.  
No. 14528. June 30, 1948.

The defendant, who exploited a line of "health foods," received unlabeled articles of food and drug in interstate commerce and labeled them on the basis of an analysis supplied by the shipper. The defendant then repacked the product and transported it in interstate commerce under her own label. A defendant, in a prosecution under the Federal Food, Drug, and Cosmetic Act, is not entitled to assert lack of intent to violate the statute as a defense.

Sections 301 (a), 403 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

It was unnecessary to determine whether the defendant fell within the exemption of the guaranty provision in Section 303 (c)(2), since the defendant had complied with the conditions set forth in Section 303 (c)(1) and was therefore exempt from the penalties provided for in the Act.

Sections 301 (a), 303 (a), 303 (c), Federal Food, Drug, and Cosmetic Act.

Section 303 (c) (1) was designed to protect innocent dealers, such as the defendant, who receive goods shipped in interstate commerce in violation of the Act.

Section 303 (c), Federal Food, Drug, and Cosmetic Act.

The defendant was an innocent dealer and should be afforded the protection of Section 303 (c)(1); the defendant was exempted from liability since she had cooperated with the Government as required by the section.

Section 303 (c), Federal Food, Drug, and Cosmetic Act.

Edward A. Kallick, Assistant U.S. Attorney, and Gerald A. Gleeson, U.S. Attorney, Philadelphia, Pa., for plaintiff.

Michael Saxe and Wesley Hurst Caldwell, Philadelphia, Pa., for defendant.

*[Prosecution Begun By Information]*

WELSH, District Judge: This is a prosecution begun by information, containing two counts, charging Bess J. Levine, an individual trading as Miracle Food Company, with violation of the Act of Congress of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. Section 301-392, known as the Federal Food, Drug, and Cosmetic Act.

*[Findings as to Defendant]*

The defendant, Bess J. Levine, is registered under the Fictitious Names Act of Pennsylvania as owner of the Miracle Food Company and has her principal place of business at 218 North 62nd Street, Philadelphia, Pennsylvania. The Miracle Food Company is the successor to Miracle Health Food Company, formerly operated at 259 South 11th Street, Philadelphia, Pennsylvania, by the defendant.

In 1936, the defendant, Bess J. Levine, commenced to operate the business of exploiting a line of "health foods." Among

the health foods and dietary remedies promoted by the defendant was the product "Protecto" represented as a culture containing large numbers of Lactic acid bacilli.

*[Findings as to Product]*

The product is manufactured by the Earp Laboratories, Caldwell (Bloomfield), New Jersey. It is shipped to the defendant unlabeled. It is then labeled by the defendant on the basis of the analysis supplied by the Earp Laboratories. Finally, the product is shipped by the defendant, repacked and under her own label in interstate commerce.

*[Stipulation Between Government and Defendant]*

The trial was without a jury and the following is the stipulation entered into by counsel for the government and for the defendant:

*STIPULATION*

It is hereby stipulated and agreed by and between counsel for the government



and counsel for the defendant, Bess J. Levine, an individual trading as Miracle Food Company, that the following facts may be considered by this Court as true and correct for the purpose of the case, and are offered by the respective parties in lieu of evidence thereof: That on or about January 29, 1947 the Miracle Food Company, 259 South 11th Street, Philadelphia 7, Pennsylvania, shipped via Super Service Motor Truck from 259 South 11th Street, Philadelphia 7, Pennsylvania, to Health Food Store, 206 North Cleveland Curb Market, Memphis, Tennessee, certain articles of foods and drugs including 12 bottles each containing 16 ounces, the said bottles bearing labels as follows: and hereinafter referred to as "Protecto."

"Protecto"

contains

Milk Whey Powder, Malt Sugar  
200,000,000 of Acidurid Bacteria  
per I. C. C.

Lactose

16 ozs.

\$1.25

Made for  
MIRACLE FOOD CO.  
Philadelphia, Pa.

Expir. date (stamped) Apr. 2, 1947

Directions

Average dose 2 tablespoons of Protecto  
after each meal or according to your  
physicians instructions.

Can be added to Tomato Juice

#### ENEMAS

Protecto is a splendid culture for Enemas. After taking enema add 2 tablespoons of Protecto to 4 oz. of fresh water and retain as long as possible. Shake well before using.

Keep Protecto in cool place.

That on March 7, 1947 Hilding C. Olson, a duly authorized inspector of the Federal Security Agency, Food and Drug Administration, purchased from the said Health Food Store, 206 North Cleveland Curb Market, Memphis, Tennessee, two bottles, each containing 16 ounces of Protecto: That the said inspector designated the said bottles of Protecto as an official sample No. 41-022 H of the Food and Drug Administration. That at the time this sample was purchased Gladys Norris, owner of the Health Food Store, the consignee, identified the said article as being portion of a shipment received by the Health Food Store on or about January 31, 1947 via Cook Truck Lines, Inc., from the Miracle Food Company, 259 South 11th Street, Philadelphia 7, Pennsylvania in response to an order previously given by the Health Food Store and covered by freight bill No. 22365, dated January 31,

1947 issued by Cook Truck Line, Inc. on which freight bill shows as connecting line reference "Super Serv. P 36907," and an invoice dated January 30, 1947 issued by Miracle Health Food Company, Philadelphia 7, Pennsylvania to Health Food Store, Memphis, Tennessee. That copies of these records were furnished the inspector by the consignee, Health Food Store, at the time of this sample purchase. That the Miracle Health Food Company, as shown on this invoice, is one and the same as Miracle Food Company located at 259 South 11th Street, Philadelphia 7, Pennsylvania:

That the said inspector paid the sum of \$2.50 by United States Government voucher for the said articles which were immediately securely wrapped and sealed and identified by him upon the labels thereof with the legend "41-022 H 3-7-47 H.C.O." and upon the official seals the legend "41-022 3-7-47 Hilding C. Olson":

That this sample so collected, identified and sealed, was delivered to the laboratory of the Food and Drug Administration. That analysis established that the article labeled in part "Protecto contains \* \* \* 200,000,000 of Acidurid Bacteria per I. C. C." contained viable acidophilus types of bacteria less than .4% of the 200,000,000 per C. C. declared on the label.

That the business address of the defendant, Bess J. Levine, trading as Miracle Food Company, through and during January 1947 was 259 South 11th Street, Philadelphia 7, Pennsylvania and that her present business address is 218 North 62nd Street, Philadelphia, Pennsylvania; that the defendant, Bess J. Levine, was at the time of shipment here involved, and is now, the sole owner of Miracle Food Company.

#### [No Doubt as to Misbranding]

1. There can be no doubt under the facts stipulated above that there was a misbranding of the food or drug in question.

#### [Lack of Intent No Defense]

2. A defendant in a prosecution under the Federal Food, Drug, and Cosmetic Act is not entitled to assert as a defense his or her lack of intent to violate the Act. *United States v. Dotterweich*, 320 U. S. 277; *United States v. Greenbaum*, 138 F. 2d 437. Justice Frankfurter speaking for the Court in *United States v. Dotterweich* stated:

"The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the convention-



al requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded or adulterated, and that the article may be misbranded or adulterated without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares . . . ' *United States v. Johnson*, 221 U. S. 488, 497-98."

[Contention of Defendant]

3. It is the contention of the defendant that she is exempt from prosecution by virtue of Section 303 (c) of the Act. Section 303 (a) provides that any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine or imprisonment or both. Section 303 (c) provides *inter alia*:

"No person shall be subject to the penalties of subsection (a) of this Section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated Section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of Section 301 (a), that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of Section 301 (d) that such article is not an article which may not, under the provisions of Section 404 or 505, be introduced into interstate commerce."

[Defendant Exempt From Penalties  
as an Innocent Dealer]

4. This Court deems it unnecessary to determine whether or not the defendant falls within the scope of the exemption contained

in subsection (2) relating to guaranty<sup>1</sup> for the reason that it is satisfied the facts and circumstances of the instant case disclose that the defendant has complied with the conditions set forth in subsection (1) and is therefore exempt from the penalties provided for in the Act. Our conclusion is substantiated by a consideration of the purpose of the exemption found in subsection (1). It is clear that it was designed to protect innocent dealers, such as the defendant, who receive goods shipped in interstate commerce. *U. S. v. Parfait Powder Puff Company*, 163 F. 2d 1008. Thus, in Senate Report No. 493, 73rd Congress, 2nd Session, accompanying S. 2800, the Senate Committee reported as follows:

"The existing law provides for a guaranty whereby a dealer who buys on faith may be protected from liability under the law. This provision has safeguarded innocent dealers and has been extremely useful in fixing responsibility on guilty shippers. It would be continued in effect by paragraph (e). The bill affords in this paragraph further protection to the innocent dealer who distributes goods he has received from interstate sources. If he has failed to secure a guaranty he can escape penalties by furnishing the records in interstate shipment, thus allowing the prosecution to lie solely against the guilty shipper."

It is clear, we think, that the Act was intended to furnish protection to innocent receivers of goods shipped to them in interstate commerce in violation of the Act. The defendant in the instant case is such an innocent dealer and should be afforded the protection. Further, the defendant is exempt from liability under the Act for the record discloses she cooperated with the Department as required by subsection (1). In April, 1947, Mr. Bell, an Inspector of the Department, came to the defendant's place of business and took some of the Protecto away with him for examination and the defendant, at his request, informed him of the name and address of the Laboratory from which she purchased it and supplied him with all data in connection therewith which he requested.

[Defendant Found Not Guilty]

Accordingly, a verdict and judgment finding the defendant, Bess J. Levine, an individual, trading as Miracle Food Company, not guilty will be entered.

Note 1.—It should be noted in passing, however, that letters of guaranty should receive a liberal, fair, and reasonable interpretation, so as to attain the object for which the instrument

is designed and the purpose for which it is applied. *Glaser, Kohn & Company v. U. S.*, 224 Fed. 84.



PASADENA RESEARCH LABORATORIES, INC., AND  
RUSSELL B. BAVOUSET v. UNITED STATES

United States Circuit Court of Appeals for the Ninth Circuit. No. 11690.

July 16, 1948. 169 F. 2d 375.

Certiorari denied, 335 U. S. 853 (1948).

The defendants were convicted of having introduced into interstate commerce drugs which were misbranded and adulterated. The Act is remedial and should be liberally construed so as to carry out its beneficent purposes.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

The Government was required to prove its case beyond a reasonable doubt, not beyond all possible doubt.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

The Circuit Court of Appeals was not concerned with the weight of the testimony adduced below; "Questions of credibility were for the trial court".

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

An appellate court will indulge all reasonable presumptions in support of the rulings of a trial court, and, in determining whether the evidence is sufficient to sustain a conviction, will consider the evidence most favorable to the prosecution.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

In a criminal action based on shipment of adulterated and misbranded drugs in interstate commerce, the defendants, seemed to insist on what would amount to a mathematical demonstration that there had been no tampering with the drugs from the date the products left the custody of the defendants to the date when the drugs were examined by the Government. Carried to its logical conclusion, such "chain of possession" theory would require the Government to prove affirmatively that each one of the many Government clerks and experts, express company employees, etc., handled and cared for the drugs so that changes could not occur while the drugs were in their custody. Such a rigorous exaction is supported by neither reason nor authority, and if the Government were obliged to establish the absence of "tampering" by every one who had any contact whatsoever with the drugs, the Act would be incapable of enforcement.

Sections 301 (a), 501 (c), 502 (a), Federal Food, Drug, and Cosmetic Act.

There are certain well-established presumptions regarding the regularity not only of the acts of public servants but also of the acts of private individuals.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Section 201 (n) of the Act provides that omissions as well as representations shall be taken into account in determining whether labeling is misleading. Scientific half-truths in labeling alone make out a case of actionable misbranding.

Sections 201 (n), 502 (a), Federal Food, Drug, and Cosmetic Act.

The Supreme Court has pointed out that deception may result from the use of statements not technically false or which may be literally true. It is not difficult to choose statements that do not deceive.

Section 502 (a), Federal Food, Drug, and Cosmetic Act.



*Pasadena Research Laboratories, Inc. et al. v. U. S.*

Hypothetical questions to Government experts dealt with supporting or evidentiary facts, and not ultimate issues; the facts inquired about were related to the ultimate issues—else the questions would have been irrelevant.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

The fairness of a hypothetical question is largely a matter that lies within the discretion of the trial judge.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

It is presumed that a trial judge before whom a case was tried considered only competent evidence in arriving at his judgment.

Section 303 (a), Federal Food, Drug, and Cosmetic Act.

John C. Stick, R. Welton Whann, and Robert M. McManigal, Los Angeles, Cal., for appellants.

James M. Carter, U.S. Attorney, Ernest A. Tolin, Chief Assistant, Norman W. Neukom, Assistant U.S. Attorney (Arthur A. Dickermann, Attorney, Federal Security Agency, of counsel), Los Angeles, Cal., for appellee.

Before GARRECHT, MATHEWS and HEALY, Circuit Judges.

GARRECHT, Circuit Judge: The appellants were found guilty on five counts of an information charging violations of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 301 *et seq.*, hereinafter referred to as the Act, in that they "did . . . unlawfully cause to be introduced . . . into interstate commerce" adulterated and misbranded drugs. The corporate appellant was fined \$3,000, and the appellant Bavouset was placed on five years' probation, imposition of sentence upon him having been suspended.

The trial was without a jury, a jury trial and special findings of fact having been specifically waived in writing.

1. *The Facts*  
(a) *"Indoform"*

It was stipulated as to Counts I and II that a number of vials of "Indoform" were shipped by the appellants on or about September 17, 1945, from Pasadena, California, to Dr. Joseph C. Bunten, Cheyenne, Wyoming. One vial was picked up as a sample by Ralph M. Davidson, a Federal Food and Drug Inspector, on or about January 24, 1946, from Dr. Bunten, and was sealed and mailed to the Food and Drug Administration at Washington, D.C., hereinafter referred to as the Administration.

The vials carried labels announcing that each cubic centimeter of the drug contained three International Units of posterior pituitary and one grain of "thyroid substance."

On February 18, 1946, Arnold E. Mason, at that time employed by the Administra-

tion as pharmacologist and analyst, examined the contents of the sample vial. He testified that he "found practically no posterior pituitary in that product, an almost immeasurable quantity." After conducting the test, Mason replaced the bottle into a locked refrigerator until the next day, when he wrapped it and put a seal on it. The vial was sent to San Francisco, according to his testimony.

Mason was asked hypothetical questions, objected to by the appellant, as to whether the drug had contained three international units on the date of shipment, September 17, 1945. The questions assumed that the product had not been exposed to the "destructive temperature" of 212 degrees, had been handled in "a normal and careful manner," and had been tested as Mason had already stated on the stand. Mason answered that it was his opinion that on the date in question "there was a quantity of posterior pituitary which was not measurable by the standard methods of measuring it, or there was none."

On March 27, 1946, Andrew G. Buell, a chemist for the Administration, stationed at San Francisco, broke Mason's seal on the paper wrapper around the vial and examined the product for "thyroid content." He testified that "There was no thyroid present whatsoever." After he made his examination, he "immediately" put his seal on the bottle. The seal was dated March 28, the day after he examined the contents.

(b) *The Deficient Pluri-B*

As stipulated, a number of vials that form the basis of Counts III and IV were shipped



by the appellants to Dr. Clement Swaim, Reno, Nevada, on July 16, 1945. Inspector Frank A. Griebeling, of the Administration, picked up two of these vials, which contained Pluri-B, from Dr. Swaim, on August 30, 1945.

The inspector sealed the vials and contents with official seals, and forwarded them by mail to the Vitamin Division of the Administration at Washington.

Hubert H. Capps, a chemist of the Administration, examined one of the vials on September 24, 1945. Although the label on the vial sets forth that this "Sterile Solution of Pluri-B" contains 50 milligrams of Thiamine Hydrochloride, per cubic centimeter, Capps testified that he found it contained approximately only 33 milligrams per cc.

The Government chemist also stated that at the time he received the vial, it had the same cap that it had at the time when he was testifying, "or one very similar to it," adding that "since this does not appear to be broken, I think that it did have that identical cap." He also said, however, that he did not make any examination of the cap to determine whether or not it was punctured in any way, "other than just looking at it."

During the direct examination of Capps, he was asked the following hypothetical question, which the appellants contend was improper because it assumed facts none of which "are supported by any evidence whatever":

"Now, assuming that the product received ordinary and reasonable care, and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather, and basing upon what you found on September 24, 1945, the amount of the B-1 or thiamine chloride that you found, have you an opinion as to what percentage or what amount that product, substance, or solution had on or about July 16, 1945, the date it was originally shipped?"

Capps replied that he believed that it did not contain more than 33 milligrams of thiamine hydrochloride per cubic centimeter.

*(c) The Contaminated Pluri-B*

According to the stipulation, a number of vials with labels, which form the subject-matter of Count VII, were shipped by the appellants on June 18, 1946, to Dr. P. M.

Ryerson, Phoenix, Arizona. The vials contained "Pluri-B," and, according to the labels, the contents were "for intramuscular or intravenous use."

On or about July 12, 1946, Maurice P. Kerr, an inspector for the Administration, collected a sample consisting of six vials and their contents, each at random from different boxes of the shipment in Dr. Ryerson's possession. The inspector marked the labels, sealed the vials with official seals, and forwarded them by express to the Administration at Washington.

Dr. Frank H. Wiley, chief of the chemical section of the medical division of the Administration, holding a doctor's degree in biochemistry, testified that he received the sample on July 23, 1946. He put the vials up to a light and found "with the naked eye" that all six of them "were very badly contaminated with undissolved material."

Dr. Wiley was asked the following hypothetical question, which the appellants assert was "bad and improper because it did not include a sufficient factual basis to support an opinion":

"Q. . . . Dr. Wiley, taking the two vials, . . . which I understand you examined about six weeks after the shipment in question here, from your knowledge of sterile solutions and from your observance of sterile solutions, your experience, are you able to express an opinion to this court as to whether or not the contents of those two vials, . . . did contain the undissolved particles you noticed there, then as of the date they were shipped, namely, on or about June 18, 1946? Your answer is yes or no. A. Yes.

"\* \* \*

"Q. . . . Will you please relate your opinion?"

The appellants object that in the foregoing questions "no mention whatever was made of the conditions to which the drug had been subjected after shipment by appellants."

Dr. Wiley's answer to the question was as follows:

"A. From experience with these materials and from general information of so-called supersaturated solutions, of which this is an example, I would say that this undissolved material was undoubtedly present on June 18th when the material was shipped. There is only one external factor of which I know that would hasten or increase the crystalliza-



tion of this material, and that would be refrigeration. I doubt very much if the mail bag in which this material was transmitted to Washington was in a refrigerator car."

The appellants comment that "even if the question was proper Wiley's opinion given in response thereto is not entitled to any weight whatever."

Other evidence relating to the drugs in question will be referred to in appropriate places in the discussion that follows.

### 2. *The Canon of Construction*

The Act is remedial, and should be liberally construed so as to carry out its beneficent purposes.

In *United States v. Dotterweich*, 320 U.S. 277, 280, the Court said of this statute:

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [Cases cited.]"

As we will point out hereafter, we are here being asked to accept defensive refinements that we believe are as gossamer-like as the traditional "shadow of a shade" of the ancient legal commentators. We have recently had occasion to construe this same statute and have endeavored to do so in the liberal spirit commanded by the Supreme Court. *Research Laboratories, Inc. v. United States* [C. C. A. 9], 167 F. 2d 410, 421. In the instant case, we do not feel disposed to depart from that same generous norm of interpretation, which we believe accords with public policy and with the spirit of the law itself.

### 3. *The Government's Burden and the Appellate Function*

The appellants seem to be laboring under a fundamental misconception regarding (1) the degree of proof required from the appellee and (2) the duty of this court in the evaluation of the evidence. Because these misapprehensions are basic, we will endeavour to clear them away at the outset.

#### (a) "Reasonable" versus "Possible" Doubt

While the appellants professedly recognize the rule that the Government must prove its case beyond a *reasonable* doubt, their briefs are replete with expressions which seem to

indicate that in reality the standard actually insisted upon is that the appellee's evidence should remove all *possible* doubt.

For example, we are twice told that "The Government failed to eliminate the possibility of the drugs having lost their strength . . . or having undissolved material formed or introduced in it . . . between the dates of shipment and the dates of the Government tests." Again, after enumerating many dire vicissitudes through which the drugs in question might have passed—such as improper handling, the use of hypodermic needles containing certain chemicals, and the like—the appellants suggest: "Any one of the above things *may* have occurred even while in the inspector's hands, or during shipment by the inspector to Washington, D.C." [Emphasis supplied.]

Elsewhere we find a variation of the same theme: "Furthermore, there was no evidence *precluding the possibility* that the drugs became adulterated and misbranded *at some time* after they had been shipped by appellants from Pasadena, California." [Emphasis supplied.] Finally, in the reply brief we find the statement that "still the Government cannot prevail because the Government introduced no evidence to show that any of the above things did not happen."

While in other portions of their briefs the appellants do complain that the Government failed to adduce certain affirmative evidence, their insistence also upon the lack of *negative* evidence indicates that they are holding the appellee to too strict a standard of proof; namely, the proof of several negatives.

In *Henderson v. United States* [C. C. A. 9], 143 F. 2d 681, 682, we said:

"The proof in a criminal case need not exclude all doubt. If that were the rule, crime would be punished only by the criminal's own conscience, and organized society would be without defense against the conscienceless criminal and against the weak, the cowardly and the lazy who would seek to live on their wits. The proof need go no further than reach that degree of probability where the general experience of men suggests that it has passed the mark of reasonable doubt."

See also *Rose v. United States* [C. C. A. 9], 149 F. 2d 755, 759.

#### (b) *The Weight of the Evidence*

In the second place, the appellants' briefs contain frequent references to the *weight* of



the evidence. For example, complaint is made that "The finding of guilty by the Trial Court is, therefore, contrary to the weight of the evidence"; that certain allegedly contradictory testimony by Mason "does nothing more, it is submitted, than detract from the weight of any of Mason's testimony"; that "the findings of guilty by the Lower Court are contrary to the weight of the evidence"; that "Mason was biased and gave contradictory testimony"; and that "the best evidence is the testimony of Bavouset," etc.

While as to this question, too, the appellants elsewhere in their briefs assert a total lack of evidence to support the Government's case, their constant insistence on the irrelevant question of the *weight* of the evidence indicates that a certain confusion on this subject exists in their minds.

To clarify the matter for once and for all, we wish to restate plainly that this court is not concerned with the *weight* of the testimony adduced below. "Questions of credibility were for the trial court." *Newman v. United States* [C. C. A. 9], 156 F. 2d 8, 10, certiorari denied *sub. nom. Cain v. United States*, 329 U. S. 760.

(c) *The Presumption Supporting the Trial Court's Judgment*

As a corollary to the above proposition, there need be only briefly mentioned the equally familiar doctrine relative to the weight that even in a criminal case should be given to the judgment or the verdict in the trial court. The rule, with its necessary implications, was thus succinctly stated by this court in *Henderson v. United States*, *supra*, 143 F. 2d at page 682:

"It is a familiar principle, which it is our duty to apply, that an appellate court will indulge all reasonable presumptions in support of the rulings of a trial court and therefore that it will draw all inferences permissible from the record, and in determining whether evidence is sufficient to sustain a conviction, will consider the evidence most favorably to the prosecution. [Cases cited.]"

4. *The Identity of the Samples*

The appellee "has no quarrel" with the proposition that the burden is on the Government to establish that in reasonable probability the testimony of its witnesses regarding the condition of the drugs as of the date of analysis substantially reflects their condition on the date of shipment.

The controversy between the parties arises in the application of this familiar principle to the facts at bar. The appellants seem to insist on what would amount to a mathematical demonstration that there was no tampering with the vials anywhere along the line, from the date the products left the custody of the appellants to the date when the drugs were examined and analyzed in Washington or San Francisco. The appellee, on the other hand, asserts that it has undertaken "to establish the identity of the samples *as of the time of shipment*, by circumstantial evidence relating to their interstate shipment, the identity of the consignees and the condition of the drugs when received by the Government chemists, together with the reasonable inferences flowing from such evidence."

We will now examine these divergent assertions in greater detail.

(a) *"The Chain of Possession"*

The appellants contend that the opinions of the Government's witnesses, based on tests made after the drugs had been shipped to Washington are "absolutely worthless because the expert witnesses had no knowledge that the alleged adulteration or misbranding did not occur enroute to the doctor's office; or in the doctor's office, or in the hands of the Government inspectors who picked up the drugs, or enroute to Washington, D.C., when shipped there by the Government inspectors."

Carried to its logical conclusion, this "chain of possession" theory would require the Government to prove affirmatively that *each* one of the many mail clerks, Administration clerks and experts, doctors, nurses, express company employees, "and others," handled and cared for the goods so that changes could not occur while the drugs were in their custody. It must also be shown that the products "were not tampered with," say the appellants.

Such a rigorous exaction regarding proof is supported neither by reason nor by authority. If the Government was obliged to establish the absence of "tampering" by every one who had any contact whatsoever with the drugs, the Act would be incapable of enforcement.

In *Lestico v. Kuehner* [Minn.], 283 N.W. 122, 125, the court derided "the unique theory" that it was incumbent to show the "chain of possession" of a punctured tire casing offered in evidence after it had been



repaired, "during the whole period from accident to trial." The court said:

"The tire had been removed and repaired in Minneapolis. The thought of objections and sustaining rulings was that no sufficient foundation could be laid except by testimony not only as to genuineness, but also the absence of tampering, from every person through whose hands the casing had passed in the meantime.

*There is no such rule and never has been.*" [Emphasis supplied.]

In quoting authorities to support their position, the appellants significantly omit two pertinent passages from their excerpts. From the opinion in *United States v. S. B. Penick & Co.* [C. C. A. 2], 136 F. 2d 413, 415, they delete the following sentences:

"But there is no hard and fast rule that the prosecution must exclude all possibility that the article may have been tampered with. [Citing *Lestico v. Kuehner, supra*] \* \* \* Here the samples were taken in the ordinary course of business for the very purpose of being retained as samples; they were put in the usual place where samples were kept to remove them from accident or meddling and there they remained, so far as appears, undisturbed. We think this showing was sufficient to justify admission in evidence of the bottles and their contents and that it was for the jury to decide how likely it was that some other substance had been substituted for what was originally put in the bottles. [Cases cited]"

Similarly, the appellants omit the following sentences from the very middle of their quotation from 32 C. J. S. § 607, at pages 457-458:

"However, it is not necessary that the article be identically the same as at the time in controversy. It is unnecessary to show an absence of tampering on the part of every person through whose hands the article has passed; as long as the article can be identified it is immaterial in how many or in whose hands it has been. A direct statement that the article was in the same condition at the time of an occurrence as at a subsequent time is not required if it sufficiently appears that it must have been in substantially the same condition."

#### (b) The Presumption of Regularity

Buttressing the natural and reasonable inferences that may be drawn from the stipulations and the testimony regarding the marking, sealing and opening of the vials

in question, there are certain well-established presumptions regarding the regularity not only of the acts of public servants but also of the acts of private individuals.

#### I. Of the Acts of Public Servants

In *United States v. Chemical Foundation*, 272 U. S. 1, 14-15, the familiar rule as to the acts of public officers is thus stated:

"The presumption of regularity supports the official acts of public officers and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties. [Cases cited]" [Emphasis supplied].<sup>1</sup>

In the instant case, this presumption of official regularity would apply not only to the methods used by the Government chemists and analysts in handling the vials, but also to the care and to the absence of tampering on the part of the postal employees through whose hands the shipments passed. *Boerner v. United States* [DC NY], 30 F. Supp. 635, 637, affirmed, 117 F. 2d 387, certiorari denied, 313 U. S. 587.

#### II. Of the Acts of Private Individuals

While the appellants reluctantly concede that there "may" be a presumption supporting the official acts of public servants, they insist that "there is no presumption whatever" with respect to "shippers," doctors, nurses, "and others."

We do not agree.

In *United States Bank v. Dandridge*, 25 U. S. 64, 69-70, Mr. Justice Story said:

"By the general rules of evidence, presumptions are continually made, in cases of private persons, of acts even of the most solemn nature, when those acts are the natural results or necessary accompaniment of other circumstances. In aid of this salutary principle, the law itself, for the purpose of strengthening the infirmity of evidence, and upholding transactions intimately connected with the public peace, and the security of private property, indulges its own presumptions. It presumes, that every man, in his private and official character, does his duty, until the contrary is proved [cases cited]; it will presume that all things are rightly done, unless the circumstances of the case overturn this presumption, according to the maxim, *omnia presumuntur rite et solemniter esse acta, donec probetur in contrarium.*"

This early decision and the doctrine that it enunciates were referred to with approval

<sup>1</sup> See also *Bowles v. Glick Bros. Lumber Co.* [CCA 9], 146 F. 2d 566, 571, certiorari denied, 325 U. S. 877; *Dunn v. Ickes* [CA DC], 115 F.

2d 36, 37, n. 8, certiorari denied, 311 U. S. 698; *Middleboro Liquor & Wine Co., Inc. v. Berkshire* [CA DC], 133 F. 2d 39, 42.



in *International Shoe Company v. Federal Trade Commission*, 280 U. S. 291, 302, where reference was made to "the familiar presumption of rightfulness which attaches to human conduct in general."<sup>2</sup>

This presumption that even private individuals do their duty and exercise due care should apply *a fortiori* to doctors and nurses, whose professional training and traditions teach them to be meticulous in the handling of preparations that are to be administered to their patients.

Indeed, in the instant case, this presumption is supported by the affirmative testimony of one of the appellants' own witnesses. Dr. Roland N. Icke, director of research at the appellants' laboratories, said while under cross-examination:

"Q. . . . It has been your practice and observation of most doctors that they try to keep their bottles in proper places, has it not, Doctor?

"A. I believe most of them do; yes.

"Q. And it is rare that you find a doctor but what he adheres to the cautions that he has been instructed; isn't that correct?"

"A. Yes."

The appellants have not pointed out, nor have we been able to find, a single scintilla of evidence in the record to indicate that any of the vials were mishandled by a single postal clerk, expressman, doctor, nurse, Government analyst, Administration mail clerk, or *any one else* who had any connection with the sealing, labeling, consignment, transmission, unwrapping, unsealing, or testing of the products in question.

The only suggestions of mishandling are in the form of *dire possibilities* conjured up by resourceful counsel. But possibilities are not proof.

### 5. The So-Called "Disclaimer"

#### (a) Should "Thyroid Substance" Contain Iodine?

It will be recalled that, although the label on the vials of "Sterile Indoform" announced that each cubic centimeter of the contents carried one grain of "thyroid substance," Buell, the Administration's chemist, found "no thyroid present whatsoever."

The appellants seek to avoid the impact of Buell's testimony by pointing out that, according to his own statement, the only thing that he examined the product for "was

for the therapeutically active ingredients of thyroid, which were the organically combined iodine products." In other words, he examined "only for iodine."

Buell also testified, however, that the label statement regarding "thyroid substance" means that each cubic centimeter contains "one grain of the active constituent of the thyroid," "as organically combined iodine." "The activity of thyroid," he explained, "depends on the organically combined iodine present in the thyroid."

The appellants freely admit that there never was any iodine in "Indoform." They point to Buell's own testimony, however, that there would be present in a thyroid gland "other things" besides iodine. From this the appellants argue that the words "thyroid substance" do not necessarily imply that the preparation contains iodine.

#### (b) At Best the Label Tells only a Half-Truth

The appellants seek to bolster up this argument by pointing out that the label itself contains the notation:

"This preparation does not contain any known therapeutically useful constituent." Since iodine is a therapeutically useful ingredient, they say, the label itself indicates that iodine is not present.

There are two answers to this argument. In the first place, this so-called disclaimer itself is untruthful. The appellant Bavouset himself admitted on the stand that posterior pituitary, which, as we have seen, is one of the ingredients of "Indoform," *does* have therapeutic value. He also testified that he "didn't manufacture" whole ovarian, another constituent, to be a meaningless product. The appellants seek—without avail, we think—to weaken the effect of this testimony by Bavouset's later lame and somewhat cryptic explanation that "In this particular solution, this form would not be measurable." In any event, we cannot say that the court erred if it believed from the evidence—as we do—that posterior pituitary and whole ovarian *do* have some therapeutic value.

Assuming, however, for the sake of argument, that the "disclaimer" does tell the truth, it cannot cure the vice of the half-truth or equivocation in the use of the expression "thyroid substance" in a preparation that contains no iodine. Section 321

<sup>2</sup> See also *Powell Bros. Truck Lines v. Piatt* [CCA 10], 92 F. 2d, 879, 880; 31 C.J.S. § 150 e, p. 840.



(n) of 21 U. S. C. A. provides that *omissions* as well as representations shall be taken into account in determining whether the labeling is misleading.

In *Research Laboratories v. United States*, *supra*, 167 F. 2d at page 418, we held that "the scientific half-truths in the labeling alone make out a case of actionable misbranding."

Specific reference to self-contradictory labels is found in *H. N. Heusner & Son v. Federal Trade Commission* [C. C. A. 3], 106 F. 2d 596, 597:

"Accordingly, the petitioner, a Pennsylvania manufacturer of cigars which contain only Pennsylvania tobacco, but are branded 'Havana Smokers,' has been ordered to cease and desist from using the word 'Havana' to designate its product. We are asked to modify this order so as to permit the retention of the word 'Havana' with an appropriate 'qualification', i.e., the legend: 'Notice. These Cigars are made in the United States and only of United States tobacco.'

"The difficulty of petitioner's position lies in the fact that the implication of the word 'Havana' is totally false. The purchaser can be guided by either label or legend, but not by both." [Emphasis supplied]<sup>3</sup>

So here, the purchaser of "Indoform" could be guided by either the labeling "thyroid substance," which implies the presence of a therapeutic ingredient, or by the "disclaimer" of the presence of *any* such ingredient. Obviously, the implication of presence and the negation of presence cannot both be true.

In the language of the day, this "Indoform" label strikes us as a bit of scientific "double-talk."

The Supreme Court has repeatedly denounced equivocation and evasion by those who come within the reach of a statute that enunciates Governmental policy. Whether the subterfuge is accomplished by suppression or contradiction, the vice is the same.

Referring to the Food and Drugs Act of 1906, the Supreme Court, in *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, 442-443, used the following language:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically

false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act."<sup>4</sup>

So here, it would have been "not difficult to choose statements" that would not deceive. The simple legend, "This preparation does not contain iodine," would have been sufficient.

#### 6. *The Hypothetical Questions*

The appellants object to certain hypothetical questions that were propounded to three of the Government's experts. These questions have already been quoted by us, either verbatim or in substance, in our outline of the facts.

##### (a) *The Questions Presented Sufficient Facts in Evidence*

The appellants' first two attacks upon these hypothetical questions may be considered together. They are (1) that the question addressed to Dr. Wiley did not contain sufficient facts to afford ground for a reasonable conclusion or opinion, and (2) that the question asked of Mason and Capps assumed facts not in evidence.

From the facts already stated, supplemented by the reasonable inferences flowing therefrom and by the presumption of regularity that, as we have seen, are firmly recognized in the law, it is clear that the hypothetical questions referred to were not objectionable. We need not labor the factual aspects further.

Moreover, it should be remembered that the rule requiring a factual basis for a hypothetical question is not applied with iron rigidity.

In *Permanente Metals Corporation v. Pista* [C. C. A. 9], 154 F. 2d 568, 569, we said:

"Moreover, it has been held in California, as elsewhere, that where a witness answers a hypothetical question not founded on all the facts of the case, the defect goes not to the competency of the evidence but merely affects its weight."

And in the earlier case of *Travelers Ins. Co. v. Drake* [C. C. A. 9], 89 F. 2d 47, 50, this court used the following language regarding the factual latitude that might be allowed:

*mission* [CCA 7], 153 F. 2d 103, 105.

<sup>4</sup> See also *Donaldson v. Read Magazine*, 333 U. S. 178, 188-189.

<sup>3</sup> See also *El Moro Cigar Co. v. Federal Trade Commission* [CCA 4], 107 F. 2d 429, 431; *Progress Tailoring Co. v. Federal Trade Com-*



"The question may be framed upon any theory of the interrogator, which can reasonably be deduced from the evidence; any assumptions may be indulged on any fact within the evidence, upon which opinion is desired by the interrogator; and facts not deemed material may be omitted. [Many cases cited] The truth of facts assumed by the hypothetical question as within the probable range of the evidence, as a basis to support the hypothetical question, is a question of fact for the determination of the jury to find with the other submitted facts upon a fair submission of the issue, and it must determine whether the basis upon which the hypothetical question rests has been established. [Authorities cited] When the question assumes a state of facts which the evidence directly, fairly, and reasonably tends to establish, and does not transcend the range of the evidence, it is not objectionable. [Cases cited]"<sup>5</sup>

(b). *The Questions Did Not Deal With "Ultimate Issues"*

The appellants further urge that all the hypothetical questions violated the "rule of law" "excluding the opinions of experts as to the ultimate issues of fact to be determined."

This objection is not well grounded. A glance at the questions discloses that in none of them is there any reference to "misbranding" or "adulterating," which are the ultimate issues in this case. Dr. Wiley was asked whether he thought that the two vials of Pluri-B contained the undissolved particles on June 18, 1946, the date on which they were shipped. The question addressed to Mason was whether the "Indoform" contained three international units of posterior pituitary on September 17, 1945. The hypothetical question directed to Capps related to the amount of thiamine hydrochloride in the Pluri-B on the date when it was shipped by the appellants, July 16, 1945.

All these questions dealt with *supporting* or *evidentiary* facts, and not ultimate issues. It is true that the facts inquired about were *related* to the ultimate issues; else the hypothetical questions would have been irrelevant,

and the appellants would now be clamoring that the questions were improper on the ground of immateriality.

In *Travelers Ins. Co. v. Drake* [C. C. A. 9], *supra*, 89 F. 2d at page 49, this court said:

"While the jury is the sole judge of the facts as to the issue of death and cause of death, that does not, however, make objectionable the opinion of a medical expert in aid of the jury to find the ultimate fact. [Many cases cited]"<sup>6</sup>

Furthermore, this court has repeatedly held that the fairness of a hypothetical question is largely a matter that lies within the discretion of the trial judge.<sup>7</sup>

(c) *The Trial Judge Is Presumed To Consider Only Competent Evidence*

Even if certain deficiencies had crept into any of the hypothetical questions—which we most certainly do not concede—in this and in other circuits it is presumed that the trial judge considered only competent evidence in arriving at his judgment.

In *Hoffman v. United States* [C. C. A. 9], 87 F. 2d 410, 411, we said:

"This case was tried by the judge and presumably he would consider only material and competent testimony."<sup>8</sup>

7. *The Appellants' Admitted Lack of Testing Equipment*

Capps said on the stand that he tested the contents of one of the vials in evidence for thiamine hydrochloride, and that he used a "Thiachrome procedure." This test was made on September 24, 1945.

Immediately following Capps as a witness was the appellant Bavouset. The latter was cross-examined at some length regarding a hearing of the Administration conducted by a Mr. Rowe on November 7, 1945. The record shows the following:

"Q. And did you not likewise state to Mr. Rowe at the hearing on or about November 7, 1945, with regard to the Pluri-B and the thiamine deficiency, that you did not have the equipment to make the thiachrome determination for thiamine and that you would have to, therefore, revise your manufacture and procedure?"

<sup>5</sup> See also *Moyer v. Aetna Life Ins. Co.* [CCA 3], 126 F. 2d 141, 144.

<sup>6</sup> See also *Francis v. Southern Pacific Company* [CCA 10], 162 F. 2d 813, 817, affirmed, 333 U. S. 445; *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos* [DC Minn.], 53 F. Supp. 746, 760.

<sup>7</sup> *Travelers Ins. Co. v. Drake* [CCA 9], *supra*, 89 F. 2d at p. 50; *United States v. Aspinwall* [CCA 9], 96 F. 2d 867, 869; *Permanente Metals*

*Corporation v. Pista* [CCA 9], *supra*, 154 F. 2d at pp. 569-570. Cf. *Moyer v. Aetna Life Ins. Co.* [CCA 3], 126 F. 2d at p. 144.

<sup>8</sup> See also *United States v. David* [CCA 7], 107 F. 2d 519, 522; *Murray v. United States* [CCA 8], 117 F. 2d 40, 45; *Gates v. United States* [CCA 10], 122 F. 2d 571, 578, certiorari denied, 314 U. S. 698; *Daniel v. United States* [CCA 8], 127 F. 2d 1, certiorari denied, 317 U. S. 641.



"A. We did not have the equipment. Now, about the revision of manufacturing procedure, that goes on almost every day."

The appellee refers to this lack as constituting "poor manufacturing controls." In resisting this charge, the appellants, in their reply brief, run into another admission:

"When the Government uses the term 'poor manufacturing controls' it undoubtedly refers to the *fact* that appellants did not always test their products at the conclusion of the manufacture." [Emphasis supplied]

All this, we think, further supports the

trial court's judgment that the appellants' products in question were so deficient or contaminated as to result in a violation of the Act.

#### 8. Conclusion

While in the foregoing discussion we have copiously referred to the transcript, we have not attempted to give a complete summary of the evidence. To have done so would have unduly lengthened this opinion.

Our careful study of the entire record, however, has convinced us that there was no error in the judgment below, and it is accordingly affirmed.

## UNITED STATES v. MARYLAND BAKING COMPANY AND SARA PIEM, AN INDIVIDUAL

United States District Court for the Northern District of Georgia.

No. 18189 Criminal. September 29, 1948.

81 F. Supp. 560.

A criminal information against the defendants was filed under the Federal Food, Drug, and Cosmetic Act, charging the shipment in interstate commerce of adulterated food. Two agents of the Food and Drug Administration had gone to defendants' plant and, when told that the manager was in conference, had asked for the next in authority. They were then directed to the plant superintendent and made a plant inspection with his cooperation. At a later date, a continuation of the inspection was had, but no express permission therefor was given by, or requested of, the manager. In the course of the inspection, various samples of the defendants' batter, flour, and finished products were secured and pictures made of a portion of the premises. The court declared that the manager had been present in the plant at the time of the inspection and that, pursuant to Section 704 of the Act, she was the proper person from whom permission to inspect should have first been requested, since she was the only one authorized to give such permission.

Sections 301 (a), 303 (a), 402 (a), 704, Federal Food, Drug, and Cosmetic Act.

Inasmuch as the plant superintendent was not the "owner, operator, or custodian" of the plant, as specified in Section 704, and since the agents of the Food and Drug Administration had not complied with the section by first requesting and obtaining permission to inspect from the manager, the court held that the inspection had not been within the terms of the statute and that the evidence obtained as a result thereof had been illegally secured.

Sections 301 (a), 303 (a), 402 (a), 704, Federal Food, Drug, and Cosmetic Act.

In a criminal prosecution against the manager and the partnership which owned the plant, the manager was entitled to assert for herself, and the partnership she represented, the illegality of the evidence obtained.

Sections 301 (a), 303 (a), 402 (a), 704, Federal Food, Drug, and Cosmetic Act.



In view of the illegality of the inspection, the court declared that defendant's motion for the suppression of the evidence obtained therefrom would be sustained, and that such evidence would be declared inadmissible in the trial of the criminal prosecution against the partnership and individual defendant.

Sections 301 (a), 303 (a), 402 (a), 704, Federal Food, Drug, and Cosmetic Act.

*[Pending Criminal Information]*

ROBERT L. RUSSELL, District Judge: A criminal information is pending in this court naming Maryland Baking Company, a partnership, and Sara Piem, an individual, as defendants, in which is charged a violation of the Federal Food and Drug Act. The partnership and individual have moved the return of certain seized property and for the suppression of evidence alleged to have been seized and secured as the result of an unlawful search. A hearing has been had at which oral testimony was received concerning the circumstances of the inspection and seizure.

*[Material Facts]*

The material facts are as follows: On September 23, 1947, two agents of the Food and Drug Administration went to the plant of the partnership and asked to see the manager, who is Miss Piem. She was engaged in a conference and the agents thereupon asked for the next in authority and were directed to Mr. Lampe who is the plant superintendent, and thereupon found him on another floor of the building. The evidence is conflicting as to exactly what conversation was had. Miss Piem is the manager of the plant and in charge of all of its operations, representing the members of the partnership, who take no part in the management of the business. Lampe is concerned only with the supervision of the building and the production of the plant, all of his authority, with the exception of the power to discharge employees, being exercised under the over-all supervision of Miss Piem. Upon the agents meeting Lampe in the bake room of the plant, they testify that they made their official position known and stated that they wished to make an inspection and that he replied in substance "all right" or "go ahead," and thereafter went through the plant with them, cooperating in the inspection. Lampe denies that any request was made or any consent given, and from the evidence the Court finds that he gave no consent but merely assumed that the officers had the right to inspect and offered no objection. However, under the view the Court takes of the law, the

question of Lampe's consent is immaterial.

After some two-hour inspection, one of the agents went to the office on the lower floor and saw the manager and received certain information as to the destination of the shipments of the plant, after informing her that he had made an inspection. The manager stated that she was entitled to the courtesy of being requested the permission to enter the plant and asked that this be secured. Two days later, on September 25th, the agents again returned to the plant and one stopped by the office to secure permission to enter, but the other, however, had already entered the plant and begun a continuation of the inspection. At a later time, the date being somewhat uncertain, but probably September 28th, a continuation of the inspection was had, but no express permission was given or requested of Miss Piem, the manager.

In the course of the inspection, various samples of the batter and flour and finished products were secured and pictures made of a portion of the premises.

Miss Piem, the manager, had never granted to Lampe, the plant foreman, or superintendent, authority to admit anyone to the plant and permission from her to enter the plant was never formally requested or secured by the agents.

*[Legality of Inspection Questioned]*

Under these facts, the question presented is whether the inspection was lawfully conducted within the terms of Title 21 U. S. C. A. Section 374 which provides for and regulates such inspections. In the application of the statute in this case, we have on the one hand the necessity for not unduly impeding the valuable work of the Food and Drug Administration, and on the other hand, the maintenance of the legal rights of the defendants. The statute provides:

"For the purposes of this chapter, officers or employees duly designated by the Administrator, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or estab-



lishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce, or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

Counsel for the defendants, movants, predicates his argument largely upon the constitutional prohibition against unreasonable searches and seizures. However, as it is concluded that the inspection did not comply with the terms of the statute, it is unnecessary to consider any constitutional question. So far as the present case is concerned, the critical words are that the employees designated by the Administrator "after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times . . . . and (2) to inspect, at reasonable times, . . . ." It is difficult to conceive how a procedure could be any more definitely spelled out than by the language quoted. The first step must be the making of a request, and there must be obtained the permission, the formal consent of the owner, the operator, or custodian of the factory, etc. Under the evidence in this case, Miss Piem was the operator and custodian. She was present and this was known to the agents. When present, she was the proper person of whom to first request and obtain permission for the inspection, and under the circumstances was the only one authorized to give permission for inspection, the results of which might (and did) subject her and the partnership, for which she was the alter ego, to criminal prosecution. It is recognized that such beneficial legislation as the Federal Food and Drug Act is entitled to a liberal construction to maintain standards of health and purity in articles of food and drugs. However, the defendants are entitled to insist upon compliance with the statute.

The strict requirement of Section 374, *supra*, is emphasized by examination of the provisions of the statute as a whole. Thus, in Section 373, making provision for the inspection of the records of interstate shipments by carriers and persons receiving food in interstate commerce, they are required merely "upon the request of an officer or employee duly designated by the

Administrator" to permit access to, and copying of records showing the movements of such foods, drugs, etc., in interstate commerce. In such an instance the statute provides the "permission," but further provides that the evidence "obtained thereby shall not be used in a criminal prosecution of the person from whom obtained." The restriction of conduct expressed by the words of Section 374, *supra*, considered in their ordinary meaning, become even more evident when the formal and prohibitory provisions of the statute contained in Section 331 (f) of Title 21, U. S. C. A. are considered. By this subsection, "The refusal to permit entry or inspection as authorized by Section 374" is prohibited and the commission of a prohibited act is by Section 333 made a misdemeanor punishable by imprisonment for not more than one year or a fine of not more than \$1,000.00, or both such imprisonment and fine, for the first violation, and for not more than three years or a fine of not more than \$10,000.00, or both such imprisonment and fine, upon a second conviction. It therefore becomes readily apparent that the words "owner, operator, or custodian," must have a definite and fixed meaning in the statutory scheme of enforcement, for they thereby become a part of the enforcement of the statute by criminal prosecution. It may be that constitutional questions lurk in the background of subparagraph (f) of Section 331, *supra*. If so, they may be reserved for another day and another case, and in any event, they would not weaken the aid given to the determination of the congressional intent as to the meaning of the words "owner, operator, or custodian."

[*Inspection Illegal*]

It is clear that Lampe was neither the "operator, or custodian" of the plant, and likewise clear that under the circumstances Miss Piem was. Since the agents did not comply with the requirements of the statute by first requesting and obtaining permission from her, the inspection was not within the terms of the statute, and the evidence secured as a result thereof was illegally secured. In this criminal prosecution she is entitled to assert for herself and the partnership she represents, the illegality of the evidence so obtained. It is undisputed that the several inspections were all a continuation of the initiatory one of September 23rd, which it is here determined was illegal.



*[Motion for Suppression of Evidence  
Sustained]*

The motion for the suppression of the evidence in this criminal prosecution should be, and the same hereby is, sustained, and such evidence declared inadmissible in the

trial of the criminal prosecution against the partnership and individual defendant.

No sufficient identification of the articles seized was presented by the evidence to support direction that they be returned.

This the 29th day of September, 1948.

## KORDEL v. UNITED STATES

United States Supreme Court. No. 30. October Term, 1948. November 22, 1948.  
335 U. S. 345.

Affirming 164 F. 2d 913. See page 343.

Affirming 66 F. Supp. 538. See page 328.

Defendant was prosecuted for having introduced misbranded drugs into interstate commerce. The alleged misbranding consisted of statements in circulars and pamphlets shipped in interstate commerce by defendant, and distributed to consumers by vendors, relating to the efficacy of the products. Some of the literature was displayed in stores in which the products were sold, some was given away with the sale of the products, some was sold independently of the drugs, and some was mailed to customers by the vendors. The literature involved in a number of counts was shipped separately from the drugs and at different times. The Court declared that the drugs and literature had a common origin and destination; that the literature was used in the sale of the drugs and explained their uses; that it constituted an essential supplement to the label attached to the package; that the products and literature were interdependent; and that it would take an extremely narrow reading of the Act to hold that the drugs were not "misbranded."

Sections 201(m), 301(a), 502(a), Federal Food, Drug, and Cosmetic Act.

A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute, since the purpose fairly to apprise men of the boundaries of the prohibited action would then be defeated. But there is no canon against using common sense in reading a criminal law so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

The Court declared that the second clause of Section 201(m) reads "accompanying such article," not "accompanying such article in the package or container," and that no reason was seen for reading the additional words into the text.

Section 201(m), Federal Food, Drug, and Cosmetic Act.

One article or thing is accompanied by another when it supplements or explains it. No physical attachment of one to the other is necessary; it is the textual relationship that is significant.

Section 201(m), Federal Food, Drug, and Cosmetic Act.

The Act cannot be circumvented by the easy device of a "sale" of the advertised matter where the advertising performs the function of labeling.

Section 201(m), Federal Food, Drug, and Cosmetic Act.

There is no indication in the legislative history of the Act that Congress had the purpose to eliminate advertising which performs the function of labeling. Every labeling is in a sense an advertisement.

Section 201(m), Federal Food, Drug, and Cosmetic Act.



Section 301(k) has a broad sweep, not restricted to those who introduce drugs into interstate commerce. It is, however, restricted to cases where the article is held for sale after shipment in interstate commerce and, unlike Section 301(a), it does not reach situations where the manufacturer sells directly to the consumer.

Sections 301(a), 301(k), Federal Food, Drug, and Cosmetic Act.

Prosecution for a violation of Section 301(a) is authorized by means of information where there is no allegation that the acts committed were done "with intent to defraud."

Sections 301(a), 301(k), Federal Food, Drug, and Cosmetic Act.

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

This case and *United States v. Urbeteit*, decided this day, are here on certiorari to resolve a conflict among the circuits in the construction of the Federal Food, Drug, and Cosmetic Act of June 25, 1938. 52 Stat. 1040, 21 U. S. C. § 301 *et seq.*

Kordel is charged by informations containing twenty counts of introducing or delivering for introduction into interstate commerce misbranded drugs. He was tried without a jury, found guilty, and fined two hundred dollars on each count. This judgment was affirmed on appeal. 164 F. 2d 913.

[Statement of Facts]

Kordel writes and lectures on health foods from information derived from studies in public and private libraries. Since 1941 he has been marketing his own health food products, which appear to be compounds of various vitamins, minerals and herbs. The alleged misbranding consists of statements in circulars or pamphlets distributed to consumers by the vendors of the products, relating to their efficacy. The petitioner supplies these pamphlets as well as the products to the vendors. Some of the literature was displayed in stores in which the petitioner's products were on

sale. Some of it was given away with the sale of products; some sold independently of the drugs; and some mailed to customers by the vendors.

[Issue Presented by Case]

It is undisputed that petitioner shipped or caused to be shipped in interstate commerce both the drugs and the literature. Seven of the counts charged that the drugs and literature were shipped in the same cartons. The literature involved in the other counts was shipped separately from the drugs and at different times—both before and after the shipments of the drugs with which they were associated. The question whether the separate shipment of the literature saved the drugs from being misbranded within the meaning of the Act presents the main issue in the case.

Section 301 (a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded.<sup>1</sup> It is misbranded according to § 502 (a) if its "labeling is false or misleading in any particular," unless the labeling bears "adequate directions for use." § 502 (f). The term labeling is defined in § 201 (m) to mean "all labels<sup>2</sup> and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

<sup>1</sup> Section 301 in relevant part read as follows:  
"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or

proffered delivery thereof for pay or otherwise.

\* \* \*

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

<sup>2</sup> The term label is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." § 201 (k).



Section 303 makes the violation of any of the provisions of § 301 a crime.<sup>3</sup>

*[Products and Literature Interdependent]*

In this case the drugs and the literature had a common origin and a common destination. The literature was used in the sale of the drugs. It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus the products and the literature were interdependent, as the Court of Appeals observed.

It would take an extremely narrow reading of the Act to hold that these drugs were not misbranded. A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute (*United States v. Resnick*, 299 U.S. 207; *Kraus & Bros. v. United States*, 327 U. S. 614, 621-622), since the purpose fairly to apprise men of the boundaries of the prohibited action would then be defeated. *United States v. Sullivan*, 332 U.S. 689, 693; *Winters v. New York*, 333 U. S. 507. But there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. See *Roschen v. Ward*, 279 U. S. 337, 339.

It would, indeed, create an obviously wide loophole to hold that these drugs would be misbranded if the literature had been shipped in the same container but not misbranded if the literature left in the next or in the preceding mail. The high purpose of the Act to protect consumers who under present conditions are largely unable to protect themselves in this field<sup>4</sup> would then be easily defeated. The ad-

ministrative agency charged with its enforcement<sup>5</sup> has not given the Act any such restricted construction.<sup>6</sup> The textual structure of the Act is not agreeable to it. Accordingly, we conclude that the phrase "accompanying such article" is not restricted to labels that are on or in the article or package that is transported.

The first clause of § 201 (m)—all labels "upon any article or any of its containers or wrappers"—clearly embraces advertising or descriptive matter that goes with the package in which the articles are transported. The second clause—"accompanying such article" has no specific reference to packages, containers or their contents as did a predecessor statute. See *Seven Cases v. United States*, 239 U. S. 510, 513, 515. It plainly includes what is contained within the package whether or not it is "upon" the article or its wrapper or container. But the second clause does not say "accompanying such article in the package or container," and we see no reason for reading the additional words into the text.

One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant. The analogy to the present case is obvious. We need not labor the point.

*[Time of Shipments Irrelevant]*

The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by pur-

<sup>3</sup> "Sec. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine."

The informations in charging violations of § 301 (a), did not allege that the acts com-

mitted were done "with intent to defraud." Hence the maximum penalty was that provided in § 303 (a), viz. imprisonment for not more than a year, or a fine of not more than \$1,000, or both. Prosecution by information was therefore authorized by the statute (see *Duke v. United States*, 301 U. S. 492) and by § 7 (a) of the Rules of Criminal Procedure.

<sup>4</sup> See *United States v. Dotterweich*, 320 U. S. 277, 280; *United States v. Sullivan*, *supra*, p. 696.

<sup>5</sup> See § 701 and § 201 (c), 1940 Reorg. Plan No. IV, § 12, 54 Stat. 231, 5 U. S. C. § 133 (u).

<sup>6</sup> The Federal Security Agency by regulation (21 C. F. R. Cum. Supp. § 2.2) has ruled: "Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce."



pose or result. And to say that the prior or subsequent shipment of the literature disproves that it "is" misbranded when introduced into commerce within the meaning of § 301 (a), is to overlook the integrated nature of the transactions established in this case.

Moreover, the fact that some of the booklets carried a selling price is immaterial on the facts shown here. As stated by the Court of Appeals, the booklets and drugs were nonetheless interdependent; they were parts of an integrated distribution program. The Act cannot be circumvented by the easy device of a "sale" of the advertising matter where the advertising performs the function of labeling.

[Contentions Made by Petitioner]

Petitioner points out that in the evolution of the Act the ban on false advertising was eliminated, the control over it being transferred to the Federal Trade Commission. 52 Stat. 114, 15 U. S. C. § 55 (a). We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under § 201 (m) (2).

There is a suggestion that the offense in this case falls under § 301 (k) of the Act which includes misbranding of a drug while it is held for sale after shipment in interstate commerce.<sup>7</sup> Since the informations contain no such charge, it is therefore claimed that the judgment must be reversed. We do not agree. Section 301 (k) has a broad sweep, not restricted to those who introduce or deliver for introduction drugs in interstate commerce.<sup>8</sup> See *United States v. Sullivan*, *supra*. Nor is it confined to adulteration or misbranding as is § 301 (a). *Id.* It is, however, restricted to cases where the article is held for sale after shipment in interstate commerce; and, unlike § 301 (a) it does not reach situations where the manufacturer sells directly

to the consumer. Cf. *United States v. Urbeiteit*, *supra*. Hence we conclude that we do not disturb the statutory scheme when we refuse to take from § 301 (a) what is fairly included in it in order to leave the matter wholly to the service of § 301 (k). The reach of § 301 (a) is in this respect longer. Such a transfer to § 301 (k) would create a new hiatus in the Act and thus disturb the pattern which we discern in it.

We have considered the other objections tendered by petitioner and find them without merit.

*Affirmed.*

Dissenting Opinion

MR. JUSTICE BLACK, with whom MR. JUSTICE FRANKFURTER, MR. JUSTICE MURPHY and MR. JUSTICE JACKSON concur, dissenting.

I agree with the court's interpretation of § 502 (a) and § 201 (m) of the Pure Food and Drug Act. These sections considered together provide a definition for the "misbranding" of drugs. I agree that a drug is misbranded within the meaning of the statute if false and misleading written, printed, or graphic matter is either placed upon the drug, its container or wrappers, or used in the sale of the drug as a supplement to the package label to advise consumers how to use the drug. I agree that false labels may, within the meaning of the statute, "accompany," that is go along with, a drug on its interstate journey even though not in the same carton, on the same train, in the same mail, or delivered for shipment the same day. But these agreements do not settle all the problems in this case.

The Pure Food and Drug Act does not purport to make all misbranding of drugs within the foregoing definition a federal offense. Congressional power to pass the Act is based upon the commerce clause. Consequently misbranding is only an offense if the misbranded drugs bear the statutorily defined relationships to interstate commerce. For illustration, if a person misbranded a drug which had not been and was not thereafter introduced into interstate commerce, there would be no violation of the federal Act, whatever violation there might be of state law.

<sup>7</sup> See note 1, *supra*.

<sup>8</sup> The purpose of § 301 (k) was described in H. Rep. No. 2139, 75th Cong., 3d Sess. 3 (1938), as follows:

"In order to extend the protection of con-

sumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."



As we pointed out in *United States v. Sullivan*, 332 U. S. 689, the Pure Food and Drug Act creates several offenses each of which separately depends upon the relationship the misbranded drug then bears to interstate commerce. Section 301 (a) forbids the "introduction or delivery for introduction into interstate commerce" of misbranded drugs; § 301 (b) forbids misbranding while the drugs are "in interstate commerce"; § 301 (c) prohibits the "receipt" of such drugs in interstate commerce; and § 301 (k) forbids misbranding while drugs are "held for sale after shipment in interstate commerce."

The twenty counts of the information upon which this petitioner's conviction rests, charge that he had introduced drugs into interstate commerce, and that "when" he so introduced the drugs, they were "misbranded . . . in that . . . statements appearing in . . . bulletins and booklets accompanying" the drugs "were false and misleading." (Emphasis supplied.) The undisputed evidence as to thirteen of these counts showed that when the drugs were "introduced" into interstate commerce for shipment, they were not within any fair meaning of the word "accompanied" by the printed matter relied on as "labeling." The evidence under one count was that the drugs were shipped July 10, 1942, while the booklets said to be "labels" were sent a year and a half later, January 18, 1944. Thus, each of these counts charged a violation of the separate and distinct offense of introducing misbranded drugs into interstate commerce, prohibited by § 301 (a). The evidence proves the offense, if any, of violation of § 301 (k), which prohibits the misbranding of drugs while held for sale after an interstate shipment.

The court's interpretation of § 301 (a) seems to me to create a new offense to

make it a crime to introduce drugs into interstate commerce if they should subsequently be misbranded, even so long as eighteen months later while held for sale. This judicial action is justified in part on the ground that the offense Congress created in § 301 (k) for holding misbranded drugs for sale after interstate shipment might not reach all situations covered by the congressionally created offense defined by § 301 (a). If as the Court believes, Congress in § 301 (k) has limited the situations for which it will direct punishment for holding misbranded articles for sale, I cannot agree that we should rewrite § 301 (a) so as to broaden its coverage. If Congress left a hiatus, Congress should fill it if it so desires. While I do not doubt the wisdom of separating these offenses as Congress has here done, we must remember that there are dangers in splitting up one and the same transaction into many offenses. See *Blockberger v. United States*, 284 U. S. 299, 304-305.

These are serious offenses. While petitioner was fined only \$200 on each count, or a total of \$4,000, the maximum allowable punishment was \$1,000 per count and imprisonment for one year, or for three years under other circumstances. § 303 (a). The approach of Congress in this field of penal regulation has been cautious. The language used by Congress in the present law in defining new offenses has been marked by precision. I think we should exercise a similar caution before reading into the "introduction to interstate commerce" offense, conduct which patently fits into the "held for sale" offense.

I would reverse the judgment here insofar as it rests on the thirteen counts in which the Government charged offenses under § 301 (a) and failed to prove them.



## UNITED STATES v. ANTONIO CORRAO

United States District Court for the Eastern District of New York. Criminal No. 40551.  
November 30, 1948.

The defendant, prosecuted for having introduced misbranded olive oil into interstate commerce, moved for judgment of acquittal or for an order dismissing the information. Prior to the motion, a jury had found the defendant guilty, but the court had set aside the verdict on the ground that it was against the weight of evidence since it rested on the squalene test, which had not been officially adopted by the Association of Official Agricultural Chemists. The defendant urged that a judgment of acquittal should have been entered and questioned the court's power to set aside the verdict and grant a new trial. The Supreme Court has upheld the authority of a trial judge to set aside a verdict and grant a new trial.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

The court declared that there had been sufficient evidence to send the question of defendant's guilt to the jury, but that the verdict had been set aside because the squalene test was a new test and had not been officially adopted; that there had been sufficient evidence to send the case to a jury, but not sufficient for a conviction on the weight of the evidence.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

Under Rule 29 of the Federal Rules of Criminal Procedure, motions for directed verdicts were abolished and motions for judgments of acquittal were to be used in their place. The court declared that defendant's motion had not been timely made.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

J. Vincent Keogh, United States Attorney; Maurice Z. Bungard, Assistant United States Attorney, of Counsel, for plaintiff.

Avrutis & Zizmor, Attorneys for defendant.

ABRUZZO, District Judge: This is a motion by the defendant seeking a judgment of acquittal or for an order dismissing the information. An information was filed on June 22, 1945, charging the defendant with a violation of the Federal Pure Food, Drug, and Cosmetic Act, 21 U.S.C.A. 321, *et seq.*

The case was tried before me and the jury returned a verdict convicting the defendant. On August 15, 1946, I set the verdict aside on the sole ground that it was against the weight of evidence.

In reverting back to my notes and the memorandum decision it appears that the information charged that cans of olive oil which the defendant sold in interstate commerce had the words "20% olive oil and 80% cottonseed and peanut oil" written thereon. The Government claimed that there was not 20% olive oil in the cans, this conclusion being based upon a test made by Government chemists known as a squalene test evolved by one Dr. Fitelson who was at the time of the trial an employee of the Government. The conviction was mainly based upon his testimony.

The evidence indicated that this particular squalene test had never been officially adopted by the Association of Official Agricultural Chemists. I felt at the conclusion of the case that as this test had not been officially adopted it would be only just to the defendant that the conviction be set aside.

More than a year has expired since I set the verdict aside and this motion is now made on the theory that, first, I should have entered a judgment of acquittal, and, secondly, my power to set aside the verdict on the weight of evidence and grant a new trial is questioned. I have no doubt that I had the power to do this.

The Supreme Court has upheld the authority of a trial judge to set a verdict aside and grant a new trial. In *Metropolitan R.R. Co. v. Moore*, 121 U. S. 558, it held (p. 570):

"So upon the whole evidence in the case the testimony in support of the cause of action, or of the defense, may be so slight, although competent in law, or the preponderance against it may be



so convincing, that a verdict may be seen to be plainly unreasonable and unjust. In many cases it might be the duty of the court to withdraw the case from the jury, or to direct a verdict in a particular way; and yet, in others, where it would be proper to submit the case to the jury, it might become its duty to set aside the verdict and grant a new trial. \* \* \*

See *United States v. Robinson*, 71 F. Supp. 9 (D.C. D.C.); *Garrison v. United States*, 62 F. (2d) 41 (C.C.A. 4th); *Aetna Casualty & Surety Co. v. Yeatts*, 122 F. (2d) 350 (C.C.A. 4th).

In support of the motion, defendant's counsel relies upon the case of *Karn v. United States*, 158 F. (2d) 568 (C.C.A. 9th). That case is not in point. Karn had been convicted in the lower court and the Circuit Court reversed a conviction, holding that there was not sufficient evidence to sustain the verdict of guilty, and, where the evidence is wholly insufficient to sustain a verdict of guilty, the Circuit Court declared that to remand the case with directions to grant a new trial would, in their judgment, be a serious invasion of the rights which accrued to the defendant in the lower court. In the instant case, there was sufficient evidence to send the question of defendant's guilt or innocence under the information to the jury, but I set the verdict aside because the squalene test was a new test and had not been officially

adopted. I ruled that there was sufficient evidence to send the case to a jury, but not sufficient for a conviction on the weight of evidence. The instant case is, therefore, clearly distinguishable from the *Karn* case.

Under Rule 29 of the Federal Rules of Criminal Procedure, motions for directed verdicts were abolished and motions for judgments of acquittal were to be used in their place. Subdivision (b) provides as follows:

"(b) *Reservation of Decision on Motion.* If a motion for judgment of acquittal is made at the close of all the evidence, the court may reserve decision on the motion, submit the case to the jury and decide the motion either before the jury returns a verdict or after it returns a verdict of guilty or is discharged without having returned a verdict. If the motion is denied and the case is submitted to the jury, the motion may be renewed within 5 days after the jury is discharged and may include in the alternative a motion for a new trial. \* \* \*

I can find no decision with respect to this particular subdivision of Rule 29, but it seems clear that the motion of the defendant is not timely made.

Based upon both of the reasons set forth in this decision, this motion is denied.

## UNITED STATES v. DR. CHARLES F. KAADT AND DR. PETER S. KAADT

United States Court of Appeals for the Seventh Circuit. Nos. 9617-18.  
December 7, 1948. 171 F. 2d 600.

The defendants were prosecuted for having introduced into interstate commerce drugs which were misbranded in that statements in accompanying printed matter, not physically associated with the drugs, falsely represented the drugs as being efficacious in the cure, mitigation, and treatment of diabetes. The first clause of Section 201(m) clearly embraces advertising or descriptive matter that goes with the package in which the article is transported; the second clause has no specific reference to packages, containers, or their contents, and the advertising matter need not travel with the drug.

Sections 201(m), 301(a), 502(a), Federal Food, Drug, and Cosmetic Act.

The court declared that since the printed matter involved had been used in the sale of the drug and advertised and explained the use of the drug, and since the drug and printed matter had moved from Indiana to a point outside the state, the court was impelled to hold that the printed matter was "labeling."

Section 201(m), Federal Food, Drug, and Cosmetic Act.



A consensus of medical opinion is a question of fact and provable as such, and it has been held that a conflict of medical opinion concerning the effectiveness of a drug also presents a question of fact. The court declared, where patients had testified as to the results obtained after being treated at defendants' clinic, and outstanding medical authorities had testified that the treatment recommended by defendants was worthless and that the opinions expressed by the authorities represented the consensus of medical opinion, that the jury's finding that the labeling was false and misleading was supported by substantial evidence.

Sections 301(a), 502(a), Federal Food, Drug, and Cosmetic Act.

In determining whether there is error in the court's instructions, the charge must be viewed as a whole.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

Physical participation is not necessary in order to have criminal responsibility attach for a violation of the Act.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.

A verdict of acquittal in a prosecution based on a scheme to defraud and the use of the mails to further such a scheme is not *res judicata* in a subsequent prosecution under the Federal Food, Drug, and Cosmetic Act, since a prosecution under such Act does not involve any question of fraud.

Sections 301(a), 303(a), Federal Food, Drug, and Cosmetic Act.  
Before KERNER and SPARKS, JJ., and LINDLEY, District Judge.

KERNER, Circuit Judge: These are appeals from a judgment sentencing each appellant to a term of imprisonment after a jury had found them guilty as charged in an indictment containing seven counts and alleging violation of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 21 U.S.C.A. § 301 *et seq.*, in that they introduced or delivered for introduction into interstate commerce misbranded drugs.

Each of the seven counts charged that appellants did, on a date stated, cause to be introduced and delivered for introduction into interstate commerce, consigned to a named individual, an article of drug; that accompanying the drug was certain printed matter; that the statements in the accompanying printed matter were false and misleading because they represented and suggested and created in the mind of the reader the impression that the drug would be efficacious in the cure, mitigation, and treatment of diabetes, whereas in fact and in truth the drug would not be so efficacious.

The printed matter consisted of (1) a letter signed by C. F. Kaadt, referring to a booklet dealing with his theory of the cause, symptoms, and effect of diabetes and the treatment of same, in which he states: "I have treated many cases that have been in a very advanced stage \* \* \*.

\* \* \* I will be pleased to see you"; (2) a leaflet beginning with the words "We do Not prescribe any Set diet"; and (3) a circular entitled "Of Great Interest to Diabetics."

Section 331(a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded. It is misbranded according to § 352(a) if its "labeling is false or misleading in any particular." The term labeling is defined in § 321(m) to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Section 333(a) makes the violation of any of the provisions of § 301 a misdemeanor.

[*Arguments for Reversal*]

Four questions are argued for reversal of the judgment. In substance appellants' contentions are (1) the misbranding, if any, must occur in the labels used, and the labels must accompany the drug into interstate commerce; (2) the representations made in the labeling were honest expressions of their opinion; (3) the court erred in instructing the jury; and (4) the doctrine of *res judicata* was applicable.

[*Printed Matter Held To Be Labeling*]

First: Appellants argue that the misbranding must occur in the labels used and



the labels must accompany the drug into interstate commerce; that there is nothing in any of the three items of printed matter that informs the patient as to how the medicine is to be used; that the ingredients of the medicine are not given in the literature and no therapeutic claim is made for it, nor does any statement appear that it is efficacious in the treatment of diabetes except as to results had in prior cases.

The record discloses that all three items of printed matter or literature are not involved in every count. The circular is involved in each count and is the only printed matter in counts 2, 5 and 7. In addition to the circular, counts 1, 3 and 4 involve the leaflet, and counts 4 and 6 involve the letter. The circumstances under which the drug and the literature were introduced or delivered for introduction into interstate commerce varied, but the general pattern was the same. A prospective patient, living outside of Indiana, addressed a letter of inquiry to appellants' clinic and in response received the printed circular and sometimes the form letter. The circular contained the following statements and representations.<sup>1</sup> The patient thereafter attended appellants' clinic, and while there received the leaflet containing diet recommendations which stated in part,<sup>2</sup> and in some instances also received a copy of the circular. Before leaving, the patient had delivered to him, or appellants later shipped to him, a supply of the drug constituting a three-months' treatment. In five of the seven counts (counts 1, 4, 5, 6 and 7) it was alleged that a supply of the drug, other than that received by the patient at the clinic, was shipped from the clinic to the patient. In those counts the shipment of the addi-

tional supply of the drug and the accompanying labeling is charged as the violative shipment.

We have already been told that the phrase "accompanying such article" is not restricted to labels that are on or in the article or package that is transported, and that the first clause of § 321(m) clearly embraces advertising or descriptive matter that goes with the package in which the article is transported. The second clause—"accompanying such article"—has no specific reference to packages, containers or their contents, and it plainly includes what is contained within the package whether or not it is "upon" the article or its wrapper or container, *Kordel v. United States*, decided by the United States Supreme Court on November 22, 1948, and the advertising matter need not travel with the drug, *United States v. Urbeteit*, decided by the United States Supreme Court on November 22, 1948. And since in our case it appears that the printed matter was used in the sale of the drug, that it advertised and explained the use of the drug, and that the drug and the printed matter moved from Indiana to a point outside of the State of Indiana, we are impelled to hold that the printed matter was "labeling" within the meaning of the Act.

[Labeling Held To Be False and Misleading]

Second: Appellants insist that the representations made in the labeling were expressions of opinion that they honestly believed. They assert that "this is a repeat of the constant quarrel existing in the medical profession as to what is proper and what is improper treatment of disease"; that a difference of judgment among med-

<sup>1</sup> "3 Months' Medical Treatment to take home with you when you leave the institute \* \* \*

\* \* \* there is real hope for the diabetic, and the possibility of recovery \* \* \*

When this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting, with internal medicine taken by mouth, and without the necessity of absence from home, work, or business, it is certain to receive the most eager consideration of every diabetic. This consideration is invited in terms of what actually has been accomplished in a large number of cases of relief and recovery.

\* \* \*

The Kaadt Diabetic Institute is the culmination of over thirty years of successful treatment of diabetics by Dr. C. F. Kaadt \* \* \*

\* \* \*

The principal method of treatment is an

internal medicine taken by mouth.

\* \* \*

In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment.

\* \* \*

The files of the Institute contain many letters from grateful and appreciative patients expressing their recovery and a return to normal living."

<sup>2</sup> "Accurate dosage is difficult so if you feel that you are not getting along as well as you should increase your dose a little. It may be necessary to double it. On the other hand, if you are taking too much decrease it a little, or put in more water. The amount of water can be decided by the patient as it causes no loss of effectiveness by diluting. Drink plenty of water."



ical men as to the best course or method of treatment does not tend to prove that either party is wholly wrong or wholly right, and that all this case reflects is that certain physicians believe in one course of treatment and other physicians believe in another course of treatment. They make the point that before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion between schools or practitioners.

In this case, the issue left to the jury was whether the labeling was false and misleading in that the statements in the printed matter represented and suggested and created in the mind of the reader and led him to believe that the drug was efficacious in the cure, mitigation, or treatment of diabetes. The labeling, as we have already observed, represented that "there is *real* hope for the diabetic, and the possibility of recovery; \* \* \* this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting \* \* \*. This consideration is invited in terms of what actually has been accomplished in a large number of cases of relief and recovery. \* \* \* In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment."

The drug or treatment consisted principally of a mixture of vinegar and potassium nitrate (saltpeter); Taka-diastase, a proprietary digestive preparation, was sometimes added, but analysis revealed no Taka-diastase because it is inactivated and destroyed in a solution as strongly acid as the vinegar medicine. To show the ineffectiveness of the treatment, there was the testimony of patients who had been treated at the clinic and who had subjected themselves to the recommended home treatment with the vinegar medicine, and the testimony of relatives of former patients who had undergone the treatment and subsequently died. Each of these histories was supported by competent medical testimony. A diabetic under competent medical care, taking insulin and on a regulated diet, with his disease under control, was induced to enter the clinic for the prescribed period. In accordance with appellants' recommendations, he decreased his dosage of insulin or discontinued it and substituted appellants' treatment. After subjecting himself

to appellants' treatment, he experienced results that commonly follow uncontrolled or improperly treated diabetes. The serious and irreparable injuries that followed included diabetic coma, permanent eye injuries, and gangrene resulting in amputation.

Outstanding medical authorities who were specialists in the treatment of diabetes, testified that the treatment used and recommended by appellants would have no effect in the treatment of diabetes; that it was worthless and absolutely of no value. These experts testified that the opinions expressed by them represented the consensus of medical opinion of the authorities on diabetes; that insulin was the only drug known to be effective in the treatment of diabetes; that a proper diet and exercise must be integrated with the dosage of insulin; and that the patient must be educated to look after his condition.

We have already held that a consensus of medical opinion is a question of fact and provable as such, *United States v. Dr. David Roberts Veterinary Co.*, 104 F. 2d 785, and it has been held that a conflict of medical opinion concerning the effectiveness of a drug also presents a question of fact, *Seven Cases v. United States*, 239 U. S. 510, and since it is not necessary in a prosecution under the Act to prove guilty knowledge or wrongful intent, *United States v. Dotterweich*, 320 U. S. 277; *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008; and *United States v. Greenbaum*, 138 F. 2d 437, we think the jury's finding that the labeling was false and misleading was supported by substantial evidence.

*[Instructions to Jury Held To Be Sufficient]*

Third: It is argued that under an instruction given the jury, the jury might return a verdict of guilty on all counts even though the unlawful distribution was entirely intrastate.

In determining whether there is error in the court's instructions the charge must be viewed as a whole, *United States v. Caruthers*, 152 F. 2d 512; and *United States v. Fleenor*, 162 F. 2d 935. The trial judge in the instant case, in an endeavor to guide the jury in its determination of whether any or all of the defendants shared the required responsibility in the conduct of the business, told the members of the jury that if they found that any or all of the defendants shared responsibility in conducting the business and that the operation



of that business resulted in unlawful distribution of misbranded drugs, the defendants who shared such responsibility might be found guilty. He also instructed the jury that the burden of proof was upon the Government to prove every material allegation of the indictment and to establish the defendants guilty beyond a reasonable doubt, and that in determining whether the defendants did have a responsible share in the conduct of the business, it must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business.

It is true, appellee did not show that in each instance all of the defendants physically participated in introducing the misbranded drug into interstate commerce. But physical participation is not necessary in order to have criminal responsibility attach for a violation of the Act. *United States v. Dotterweich, supra*, 284, 285, and *United States v. Parfait Powder Puff Co., supra*.

Appellants also complain of the form of the verdicts. It is claimed the court failed to instruct the jury that defendants could be found guilty on some counts and not guilty on others. And they complain of an instruction which told the jury that the Government need not prove that all of the statements in the labeling were false or misleading, and that if the jury found that any one of the claims or statements in the labeling was false or misleading it might find that the drugs in question were misbranded. The criticism heaped upon the instruction is that all three items of printed matter were not involved in each of the counts, and that in deliberating on a particular count, the jury might have considered items of printed matter not involved in that count. But the court also told the jury that it might consider each separate item, and in the counts where more than one piece of printed matter was involved, it might consider the effect of the combined influence of all types of printed matter involved.

The record discloses that no objection was taken to the form of the verdicts or to the giving of this instruction. In this state of the record, under Rule 30 of the Federal Rules of Criminal Procedure, 18 U.S.C.A. foll. § 687, appellants are pre-

cluded from a review. We have, however, considered the points raised. We think the trial judge made it clear to the jury that each defendant could be found either guilty or not guilty on each of the counts, and that it was told that in weighing the evidence in a particular count it should consider only the items of printed matter involved in that count. There was no error committed by the court in instructing the jury.

[*Res Judicata Held To Be Inapplicable*]

Fourth: Appellant Charles F. Kaadt contends that the court erred in refusing to invoke the doctrine of *res judicata*.

To be sure, the doctrine of *res judicata* is applicable to criminal as well as civil proceedings, and operates to conclude those matters in issue which have been determined by a previous verdict, even though the offenses be different. *Sealfon v. United States*, 332 U. S. 575. In our case it appears that during the trial Kaadt offered in evidence the verdict of a jury and the opinion of the District Court in 1940 in the case of *United States v. Charles F. Kaadt*, 31 F. Supp. 546. The indictment in that case charged him with a scheme to defraud and the use of the mails to further such a scheme. He asserts that the question and issue passed upon in the prior action dealt with the therapeutic value of his medicine, and argues that that issue can not again be litigated in this case. He should not be vexed more than once for the same cause. In support of his argument he cites, among other cases, *United States v. Oppenheimer*, 242 U. S. 85; *Oklahoma v. Texas*, 256 U. S. 70; and *Tait v. Western Maryland Railway Co.*, 289 U. S. 620.

Counsel for appellee concedes, as he must, the propriety of invoking *res judicata* when the issues have previously been tried and determined, but to avoid the application of the doctrine, he points to the fact that in a scheme to defraud the significant fact is the intent and purpose, and that the two essential elements of the offense of using the mails to defraud (18 U.S.C.A. § 338) are the existence of a scheme to defraud and the placing or causing to be placed in the post office a letter, post card, package, writing, circular, pamphlet, or advertisement, for the purpose of executing the scheme. *Fournier v. United States*, 58 F. 2d 3; *United States v. Lowe*, 115 F. 2d



596; and *United States v. Cohen*, 145 F. 2d 82.

We agree with appellee that it is impossible from this record to ascertain on what ground the jury acquitted Kaadt of the offense of using the mails to defraud. But the instant prosecution does not involve any question of fraud. The misbranding charged is based on § 352(a) of the Act which provides that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. And *Sealfon v. United States*, *supra*, is of no aid to appellant for the reason that in the unique circumstances of that case, the

jury's verdict in the conspiracy trial was a determination favorable to Sealfon of the facts essential to a conviction of the substantive offense. Appellee in the present case was not required to prove intent to defraud. Thus the offense of using the mails to defraud and the offense of introducing or delivering for introduction into interstate commerce misbranded drugs are not the same, and hence there is no *res judicata*. Compare *United States v. Five cases*, 156 F. 2d 493.

The judgment of the District Court is affirmed.

---







## REVIEW CASES

### A. E. STALEY MANUFACTURING COMPANY v. SECRETARY OF AGRICULTURE AND FEDERAL SECURITY ADMINISTRATOR

United States Circuit Court of Appeals for the Seventh Circuit. No. 7470.  
May 22, 1941, and June 12, 1941. 120 F. 2d 258.

A petition was filed to set aside an order of the Secretary of Agriculture promulgating a regulation establishing a definition and standard of identity for sweetened condensed milk. The regulation permitted the use of sucrose and dextrose but not of petitioner's product, corn syrup. It was held that the petitioner had standing to seek review of the order, and that the record presented an actual controversy.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Under the Act, the Secretary must promulgate reasonable regulations that are in compliance with the statute. The court examines the evidence, not to make findings for the Secretary, but to ascertain whether his findings are properly supported.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

No finding had been made that sucrose and dextrose were the only saccharine ingredients in sweetened condensed milk. Unless a specific finding were made with reference to corn syrup, or an exclusive finding made with respect to sucrose and dextrose, the interests of the consumer would not have been given the consideration Congress had in view. The case was remanded, therefore, so that the fact finder could disclose the basis of his order, and so that a specific finding with reference to corn syrup, or an exclusive finding with respect to dextrose and sucrose, might be made.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Charles C. LeForgee, Carl R. Miller, Decatur, Ill., for petitioner.

Mastin G. White, Washington, D. C., for respondent.

Before EVANS, and KERNER, Circuit Judges, and LINDLEY, District Judge.

#### *[Nature of Proceeding]*

KERNER, Circuit Judge: Petitioner seeks to set aside an order of the Secretary of Agriculture promulgating a regulation fixing and establishing a definition and standard of identity for sweetened condensed milk, pursuant to § 701 (f) (1) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 371 (f)(1). The Federal Security Administrator was joined with the Secretary of Agriculture as a respondent, because the functions of the Secretary under the Act had been transferred to the Administrator under Reorganization Plan No. IV (5 Fed. Reg. 2421 (1940)), promulgated under the Reorganization Act of 1939 (5 U. S. C. A. § 133).

This proceeding was instituted by "notice of public hearing" filed in conformity with subsection (e) of § 701 of the Act, (§ 701, 52 Stat. 1055, 21 U. S. C. A. § 371 (e)). The notice fixed the time for the purpose of

holding a public hearing precedent to the promulgation of a regulation establishing a definition and standard of identity for sweetened condensed milk.

From the testimony of expert chemist witnesses it appears that a saccharine is used as a preservative and sweetening agent used by manufacturers of sweetened condensed milk for retail trade and that a mixture of sucrose and dextrose has been used to some extent for bulk or wholesale trade. It also appears that the adaptability of any particular saccharine ingredient for use in making sweetened condensed milk involves its reaction under the process and the results obtained, and that viscosity, crystallization, taste, solubility, thickness, and color must be considered.

#### *[Use of Corn Syrup]*

Petitioner appeared at the hearing and offered evidence to the effect that corn syrup is a suitable sweetening ingredient



in sweetened condensed milk; that from a nutritional standpoint, mixtures of sweet milk and sugars, especially sucrose, levulose, lactose and commercial glucose, commonly known as corn syrup, are physiologically essentially equivalent, interchangeable, and equal in value, and might be substituted one for the other; that corn syrup has about the same physiological effect on consumers as other sugars; that a definition of sugar restricted to mean only sucrose, in sweetened condensed milk, would be an injustice to the consumer and that a reasonable definition and standard for the best interest of consumers should read in effect "a mixture of sweet milk and sucrose, dextrose, levulose or any other digestible sugars."

There is no evidence in the record of a prior commercial use of corn syrup in the manufacture of sweetened condensed milk.

[Order of Secretary of Agriculture]

On June 28, 1940, upon consideration of the evidence received at the hearing, the Secretary of Agriculture made his findings of fact and stated his conclusion. He found that the liquid or semi-liquid food prepared by evaporating part of the moisture from a mixture of the sweet milk of cows and a saccharine ingredient is commonly known as sweetened condensed milk and that the saccharine ingredient in sweetened condensed milk is refined sugar (sucrose) or any mixture of refined sugar (sucrose) and refined corn sugar (dextrose). Based upon those findings he issued an order promulgating the regulation fixing and establishing the definition now involved, the pertinent portion thereof reading as follows: "Sweetened Condensed Milk is the liquid or semi-liquid food made by evaporating a mixture of sweet milk and refined sugar (sucrose) or any combination of refined sugar (sucrose) and refined corn sugar (dextrose)."

Petitioner now contends that the findings are not supported by substantial evidence, that the Secretary of Agriculture failed to make a finding that corn syrup (glucose) is a saccharine ingredient of sweetened condensed milk, and that he did not include corn syrup in the regulation promulgated.

[Interest of Petitioner]

At the outset we are met with respondents' contention that the petition should be

dismissed for lack of jurisdiction over the subject matter. They insist we should not listen to a party who complains of a grievance which is not his. *Interstate Commerce Com. v. Chicago, R. I. & Pacific Ry.*, 218 U. S. 88, 109. On the other hand, petitioner insists that this case presents an actual controversy, and that it is a "person who will be adversely affected by such order."

In support of its contention petitioner's counsel asserts that this case involves a real and substantial controversy admitting a specific relief through a decree of conclusive character and it is a person who will be adversely affected by the order. He calls our attention to § 701 (f)(1) of the Federal Food, Drug, and Cosmetic Act defining our jurisdiction to review the Secretary's order, which reads thus:

"In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may \* \* \* file a petition with the Circuit Court of Appeals \* \* \* for a judicial review of such order."

The argument continues: "The whole thought behind the phrase 'any person who will be adversely affected,' is that it was carefully designed and constructed to allow the orders of the Secretary to be contested by those not only adversely affected at the time and date of the order's promulgation, but also those who in the future "will be" adversely affected and concludes "petitioner's interests are now and will in the future certainly be adversely affected," and "petitioner has suffered and will continue to suffer a direct injury in being deprived of a part of its right to engage in interstate commerce."

Petitioner is not engaged in the sale of sweetened condensed milk, but is engaged in the manufacture and sale of corn syrup. In its petition it alleges that the effect of the order is adverse to its interests and will prevent the sale of its corn syrup to the condensed milk industry for use as a saccharine ingredient in sweetened condensed milk.

[Presence of Controversy]

In support of the contention that this court lacks jurisdiction, respondents rely



*Staley Mfg. Co. v. Secretary of Agriculture et al.*

upon the cases set forth in the footnote.<sup>1</sup> It is unnecessary to review these cases. It will be enough to say that we have considered them and believe they are not in point. We think the record does present an actual controversy as to the validity of the order, that petitioner is within the provision of the Act entitling it to review, and that we have jurisdiction.

[*Legality of Order*]

We now come to the question whether the order of the Secretary is in accordance with law.

The Federal Food, Drug, and Cosmetic Act, by §341, empowered the Secretary to promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, whenever in his judgment such action will promote honesty and fair dealing in the interest of consumers, and by § 371 (e) he is required to base his order on substantial evidence of record at the hearing and to set forth as part of the order detailed findings of fact on which the order is based.

In considering the previous Food and Drug Act, the provisions of which were similar to the provisions of the Act we are now interpreting, the Supreme Court in *United States v. Antikamnia Chemical Company*, 231 U. S. 654, 665, said: "The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying." In exercising the authority granted by the Act now involved, the Secretary must promulgate reasonable regulations that are in compliance with the Act, such as will promote honesty and fair dealing in the interest of consumers. *Nolan v. Morgan*, 3 F. Supp. 143 and 69 F. (2) 471. He is the fact-finding body. This court examines the evidence, not to make findings for the Secretary but to ascertain whether his findings are properly supported.

[*Sufficiency of Finding*]

In the instant case the Secretary made no finding of fact that refined sugar (sucrose) and refined corn sugar (dextrose) are the only saccharine ingredients in sweetened condensed milk. While it is true that the

requirement of essential findings does not require an impracticable exactness, nevertheless we think that unless a specific finding is made with reference to corn syrup or an exclusive finding made with reference to refined sugar and corn syrup, the interests of the consumers have not been given that consideration which Congress had in view; consequently, the order is not made in accordance with law.

## Petition for Rehearing

KERNER, Circuit Judge: The petitioner adduced evidence at the hearing, which is undisputed, which appears to constitute "substantial evidence of record," but which the Secretary of Agriculture ignores completely in its order. The statute provides that the Secretary "shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based."

[*Petitioner's Complaint*]

In effect petitioner complained that the administrative fact finder did not consider the evidence in question. Certainly the right to present evidence is a barren one if the trier of fact fails to consider it. *Morgan v. United States*, 298 U. S. 468, 304 U. S. 1. Yet it is impossible to tell from the record whether the Secretary of Agriculture weighed the evidence and cast it aside in the exercise of his administrative discretion. Consequently, the uninformed petitioner was encouraged to resort to further litigation, and a review court finds itself helpless to exercise its limited judicial review with any degree of propriety.

[*Disclosure of Basis for Order*]

It seems to us that respect for the rights of parties before it and pride in the proper dispensation of administrative justice, would compel administrative bodies to make their positions clear and thereby enable all to understand the basis of their decisions. In a recent case the Supreme Court has observed that "The administrative process will best be vindicated by clarity in its exercise." *Phelps Dodge Corp. v. National Labor Relations Board*, decided April 28, 1941.

<sup>1</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U. S. 227, 239-241; *Alabama Power Co. v. Ickes*, 302 U. S. 464, 478-479; *Edward Hines Trustees v. U. S.*, 263 U. S. 143, 148-149; *Massachusetts v. Mellon*, 262 U. S. 447, 488; *United States v. Merchants & Ass'n*, 242 U. S. 178, 186-188; *Pittsburg & W. Va. Ry. v. United States*, 281

U. S. 479, 486-487; *Moffat Tunnel League v. United States*, 289 U. S. 113, 119; *Tennessee Power Co. v. T. V. A.*, 306 U. S. 118, 139-140; *Sprunt & Son v. United States*, 281 U. S. 249, 256-257; and *New Orleans, M. & T. Railroad Co. v. Ellerman*, 105 U. S. 166, 173-174.



We therefore have remanded this case and have asked the fact finder to disclose the basis of its order. We also suggested that a specific finding may be made with reference to corn syrup, or an exclusive finding with reference to refined sugar and corn sugar. Perhaps an explanation as to its disposition of petitioner's evidence would be sufficient. We do not think, as does the respondent,

that this disposition of the case requires "anything unreasonable or impracticable in regard to findings. *Florida v. United States*, 292 U. S. 1, 9; *United States v. Louisiana*, 290 U. S. 70, 78."

The concluding paragraph in our opinion should be deleted, and it is so ordered.<sup>1</sup> The petition for rehearing is denied.

**TWIN CITY MILK PRODUCERS ASSOCIATION AND DES  
 MOINES COOPERATIVE DAIRY v. HONORABLE  
 PAUL McNUTT, FEDERAL SECURITY ADMIN-  
 ISTRATOR, AND AMERICAN DRY MILK  
 INSTITUTE, INC., AND NATIONAL CO-  
 OPERATIVE MILK PRODUCERS  
 FEDERATION, INTERVENERS**

United States Circuit Court of Appeals for the Eighth Circuit. No. 505,  
 Original. May Term, 1941. September 9, 1941. 122 F. 2d 564.

See *Twin City Milk Producers Association and Des Moines Cooperative Dairy v. McNutt et al.*, page 403.

A petition was filed to review an order of the Federal Security Administrator establishing a definition and standard of identity for skim milk as a human food. The promulgating authority is a quasi-legislative power. The statute authorizes its exercise when, in the Administrator's judgment, such action will promote honesty and fair dealing in the interests of consumers. His right to make the judgment is equivalent to a discretionary power to act, which cannot be judicially reviewed.

Section 401, Federal Food, Drug, and Cosmetic Act.

Such a judgment is intended to be the foundational basis of the Administrator's official action. In order for his order to be given affirmative judicial approval, it would have to be indicated that such judgment had actually been made the basis for his action.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The regulation was not held invalid because of failure to show that the Administrator's action rested on the foundational basis of the exercise of his judgment that the promulgation of the regulation would promote honesty and fair dealing in the interest of consumers. The cause was remanded to the Administrator, however, for if official action actually rests upon a proper basis, and the recitations necessary to demonstrate such fact have simply been inadvertently omitted, there is no sound reason why this ought not to be permitted to be shown.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

<sup>1</sup> The paragraph deleted read as follows:  
 "Our conclusion is that the order of the Secretary of Agriculture should be reversed and that the cause be remanded with instruc-

tions for such further proceedings as may be deemed advisable and not inconsistent with the views herein expressed."



*Twin City Milk Producers Ass'n et al. v. McNutt et al.*

Since the record showed that the presiding officer had limited the scope of the administrative hearing, under the published notice, to the question of proper standards for human food only, and the Administrator had declared that the regulation had no application to skim milk for animal feed, the petitioner's contention that the regulation was unreasonable because no distinction had been made between skim milk for human consumption and skim milk for animal feed was not well taken.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

What was the common or usual name of the product involved, and whether its use in a regulation would be practicable for administrative purposes, were questions for the Administrator. The court would not be at liberty to disturb his determination if based upon substantial evidence.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Where several common or usual names for a food product are found to be in general ultimate consumer use, a reasonable construction of the Act does not require that the Administrator be prohibited from adopting more than one term or designation in promulgating an appropriate regulation to promote honesty and fair dealing in the interest of consumers.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

A change of personnel in an administrative agency or tribunal during the course of a hearing, or at any time before the issuance of a final order on the hearing, does not invalidate the order.

Sections 401, 701 (c), 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Petitioner's contention that the order should be held invalid on the ground that the Administrator had not read the record before the issuance of his order is without foundation, notwithstanding the fact that only six days intervened between the transfer of the duties of the Secretary of Agriculture to the Federal Security Administrator and the latter's promulgation of the regulation. An official recitation of official regularity in an administrative order can hardly be overcome by mere implicational argument.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Louis E. Hart (W. E. Rumble, Addison M. Parker, and Charles W. Wilson on the brief) for petitioners and interveners.

William W. Barron, Attorney, Department of Justice (Wendell Berge, Assistant Attorney General, Victor E. Anderson, U. S. Attorney, Melva M. Graney, Attorney, Marc C. Reno, Attorney, Department of Justice, and William Goodrich, Attorney, Federal Security Administration, on the brief) for respondent.

Before WOODROUGH, JOHNSEN and VAN VALKENBURGH, Circuit Judges.

*[Nature of Proceeding]*

JOHNSEN, Circuit Judge: This is a petition to review an order of the Federal Security Administrator, fixing a definition and standard of identity for "dried skim milk, powdered skim milk, skim milk powder," as a human food.<sup>1</sup>

*[Authority for Promulgation of Regulation]*

The regulation was promulgated under section 401 of the Federal Food, Drug and

Cosmetic Act, 52 Stat. 1046, 21 U. S. C. A. § 341, which provides:

"Whenever in the judgment of the Secretary (of Agriculture) such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container . . ."

<sup>1</sup> The petition was filed under § 701 (f) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. A. § 371 (f).



At the time the order was issued, the authority of the Secretary of Agriculture under the Act had been transferred to the Federal Security Agency.<sup>2</sup>

[*Text of Regulation*]

The regulation is as follows:

"§ 18.540. *Dried Skim Milk, Powdered Skim Milk, Skim Milk Powder—Identity.* Dried Skim Milk, Powdered Skim Milk, Skim Milk Powder, is the food made by drying sweet skim milk. It contains not more than five per cent of moisture, as determined by the method prescribed in 'Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists,' Fourth Edition, 1935, page 282, under the caption 'Moisture-Tentative.' The term 'skim milk' as used herein means cows' milk from which the milk fat has been separated."<sup>3</sup>

[*First Contention of Petitioners*]

The first contention of petitioners and interveners is that the order should be declared invalid because it does not show that the regulation was promulgated on the basis or for the purpose authorized by the statute. Under previous declarations of the Supreme Court, there is merit in this contention.

[*Necessary Requirement for Administrator's Order To Receive Judicial Sanction*]

The promulgating authority granted to the Administrator is a quasi-legislative power. The statute authorizes its exercise when, in his judgment, such action will promote honesty and fair dealing in the interest of consumers. Such a judgment is intended to be the foundational basis of his official action. His right to make the judgment is of course equivalent to a discretionary power to act, which cannot be judicially reviewed. *United States v. George S. Bush & Co., Inc.*, 310 U. S. 371, 380, 60 S. Ct. 944, 84 L. Ed. 1259. But where action is undertaken by him, the statute contemplates that he shall not arbitrarily have attempted to exercise his power, but only upon a conscientious judgment derived from a consideration of the facts and conditions in the situation to which the regulation is to be applied. Absent the right to a direct judicial review of the order, the presumption of regularity which ordinarily attaches to official action would probably be

conclusive of the question.<sup>4</sup> But where a court is charged with the duty of reviewing the validity of an administrative agency's order, it has, up to the present time at least, refused the stamp of judicial approval, unless the order affirmatively demonstrated a compliance with all express and implied conditions underlying the exercise of the power. And so here, if it was the Administrator's judgment that his action would promote honesty and fair dealing in the interest of consumers, this fact would be conclusive of his right to exercise the regulatory power; but, for his order to be given affirmative judicial approval, as Congress has required in making provision for a review proceeding, it would have to be indicated that such a judgment was actually made the basis of his action.

This requirement is not intended as an arbitrary symbol. The great liberal minds of the Supreme Court, which have declared the need for the prescription, can hardly be accused of being worshippers of mere form. During an evolutionary period, it is a precaution that undoubtedly has aided in fostering public confidence and in winning acceptance for the processes of administrative law. Possibly it has served to safeguard against hasty or arbitrary action, by reminding those, to whom the power has been given, of their necessary responsibility in the exercise of that power. Doubtless, it has assuaged the legalistic conscience, by the assurance that only responsible action has been taken. And finally, it has facilitated the mechanics of sound and orderly judicial review. Perhaps the time may come when such a judicial precaution will no longer be thought necessary, but the expressions of the Supreme Court down to the present time give us no right to make such a departure in the present case.

[*U.S. Supreme Court Authorities*]

In the very recent case of *Phelps Dodge Corporation v. National Labor Relations Board*, 313 U. S. 177, 61 S. Ct. 845, 85 L. Ed. 753, the cause was remanded to the Board on the ground that its order, directing the reinstatement of certain employees who had obtained substantially equivalent employment, did not specifically state that such remedial action was taken to effectuate the policies of the Act. Mr. Justice

<sup>2</sup> Reorganization Plan No. IV, effective June 30, 1940, 5 Fed. Reg. 2421 (1940), 5 U. S. C. A., Note following § 133t.

<sup>3</sup> 5 Fed. Reg. 2543 (1940).

<sup>4</sup> See *United States v. Chemical Foundation, Inc.*, 272 U. S. 1, 14, 15, 47 S. Ct. 1, 71 L. Ed. 131; *Philadelphia & Trenton R. R. Co. v. Stimpson*, 14 Pet. 448, 458, 10 L. Ed. 535.



*Twin City Milk Producers Ass'n et al. v. McNutt et al.*

Frankfurter, speaking for a majority of the Court, said:

"The administrative process will be best vindicated by clarity in its exercise. Since Congress has defined the authority of the Board and the procedure by which it must be asserted and has charged the federal courts with the duty of reviewing the Board's order . . . it will avoid needless litigation and make for effective and expeditious enforcement of the Board's order to require the Board to disclose the basis of its order. We do not intend to enter the province that belongs to the Board, nor do we do so. All we ask of the Board is to give clear indication that it has exercised the discretion with which Congress has empowered it. This is to affirm most emphatically the authority of the Board."

In *United States v. Baltimore & Ohio Railroad Co.*, 293 U. S. 454, 463, 55 S. Ct. 268, 79 L. Ed. 587, where an Act of Congress authorized the Interstate Commerce Commission to prescribe by rule specific devices or changes in equipment, when required to remove "unnecessary peril to life or limb," an order of the Commission which directed the installation of such devices, without any finding that the substitution was required to remove "unnecessary peril to life or limb," was held void. Mr. Justice Brandeis' opinion states:

"The power to make the determination whether the proposed device or change is so required, vests in the Commission. But its finding to that effect is essential to the existence of authority to promulgate the rule; and as Congress has made affirmative orders of the Commission subject to judicial review \* \* \* the order may be set aside unless it appears that the basic finding was made."

In *United States v. Chicago, Milwaukee, St. Paul & Pacific Railroad Co.*, 294 U. S. 499, 504, 55 S. Ct. 462, 79 L. Ed. 1023, Mr. Justice Cardozo similarly declared:

"This court has held that an order of the Interstate Commerce Commission is void unless supported by findings of the basic or quasi-jurisdictional facts conditioning its power. \* \* \* 'In the absence of such findings, we are not called upon to examine the evidence in order to resolve opposing contentions as to what it shows or to spell out and state such conclusions of fact as it may permit.' *Florida v. United States*, (282 U. S. 194, 215, 51 S. Ct. 119, 75 L. Ed. 291)."

Mr. Chief Justice Hughes also gave recognition to the rule, in *Panama Refining Co. v. Ryan*, 293 U. S. 388, 432, 55 S. Ct. 241, 79 L. Ed. 446, when he said:

"If the citizen is to be punished for the crime of violating a legislative order of an executive officer, or of a board or commission, due process of law requires that it shall appear that the order is within the authority of the officer, board or commission, and, if that authority depends on determination of fact, those determinations must be shown."

The failure of the order to show that the Administrator's action rested on the foundational basis of the exercise of his judgment that the promulgation of the regulation would promote honesty and fair dealing in the interest of consumers would, under some of the decisions of the Supreme Court referred to above, justify us in declaring the regulation invalid. In the most recent decision of the Court, however, where such a situation has been involved, *Phelps Dodge Corporation v. National Labor Relations Board*, *supra*, the need and propriety of a more tolerant and flexible procedure has been recognized, where the administrative action relates to the public interest, and not to mere private rights. There the cause was remanded to the National Labor Relations Board, to permit it to disclose what was the actual basis of its action.<sup>5</sup> If official action actually rests upon a proper basis, and the recitations necessary to demonstrate this fact have simply been inadvertently omitted, there is no sound reason why this ought not to be permitted to be shown. Certainly, judicial responsibility to the public interest, as well as Congressional intent, will be more effectively served in this manner than by unnecessarily delaying administrative action and inviting repetitive litigation. Such a procedure will accordingly be adopted in the present case.

#### [Other Contentions of Petitioners Discussed]

Petitioners and interveners seek to have the regulation declared void on other grounds also, but all of these are without merit. Thus it is argued that the definition and standard of identity fixed by the Administrator would be unreasonable because no distinction was made between dried skim milk for human consumption and that used for animal feed. The record shows that the trial examiner or presiding officer, before

<sup>5</sup> A similar practice was followed in *A. E. Staley Manufacturing Co. v. Secretary of Agri-*

*culture*, 7 Cir., 120 F. 2d 258, 261.



whom the hearing was held, limited the scope of the hearing, under the published notice, to the question of proper standards for human food only. The Administrator, in denying petitioners' request for a rehearing, declared by letter that the regulation had no application to dried skim milk for animal feed, for which he was not prepared to attempt to prescribe standards. Petitioners applied to this Court under 21 U. S. C. A. § 371 (f) (2), for leave to adduce additional evidence, upon the question of proper standards for animal feed, which application we denied on the basis of the Administrator's showing in resistance thereto, that the regulation did not cover animal feed and that such evidence would therefore be immaterial. The Administrator necessarily could not be compelled to fix a definition and standard of identity for animal feed use. His specific construction of the regulation for purposes of this judicial review and the court's acceptance thereof would clearly, as a matter of due process, preclude any subsequent attempt on the part of the Administrator, without notice and further hearing under 21 U. S. C. A. § 371 (e), to enforce the regulation against animal feed, which petitioners purport to fear.

It is further contended that the use of the term "skim milk" is arbitrary and unreasonable, because it tends to create a derogatory impression in the public mind of the quality or food value of the product. The American Dry Milk Institute, which was an association of producers of skim milk powder, had been trying to foster the use in the trade of the designation "dry milk solids not over 1½% fat," and petitioners and interveners asked the Administrator to adopt this term.

The statute required the Administrator, in fixing a definition and standard of identity for a food, to do so "under its common or usual name so far as practicable." What was the common or usual name of the food product here involved, and whether its use in a regulation would be practicable for administrative purposes, were questions for the Administrator, on which we would not be at liberty to disturb his determination, if based upon substantial evidence. Such substantial evidence is contained in the record in this case. The Administrator was not required to hold it impracticable, for regulation purposes, to use what the evidence sufficiently showed to be the common

or usual name of a product among ultimate consumers, merely because such a designation might not be as conducive to sales by producers as some term of commercial coinage and glossing. The Administrator's obligation under the statute was simply the promotion of honesty and fair dealing in the interest of consumers. While he would have no right to adopt a designation for the purpose of destroying trade in a legitimate food product, there could ordinarily be no arbitrariness involved in using the common or usual name of such a product for regulation purposes.

It is claimed that the adoption of three designations, "dried skim milk," "powdered skim milk," and "skim milk powder," was not a compliance with the provisions of the Act requiring the use of the "common or usual name." The right to employ any or all of the three synonymous common or usual names would appear to be more of an advantage than a detriment to petitioners and interveners. Where several common or usual names for a food product are found to be in general ultimate consumer use, a reasonable construction of the Act does not require that the Administrator be prohibited from adopting more than one term or designation in promulgating an appropriate regulation to promote honesty and fair dealing in the interest of consumers. Nor is such a strict singular construction of the term "common or usual name" required *per se*, in view of the general congressional declaration in 1 U. S. C. A. § 1, that "In determining the meaning of any Act or resolution of Congress, passed subsequent to February 25, 1871, words importing the singular number may extend to and be applied to several persons or things."

It is argued also that the Administrator could not legally promulgate a resolution on the basis of the hearing had and the evidence adduced while the Food and Drugs Administration was under the supervision of the Secretary of Agriculture. No authority is cited in support of this contention. There is no sound reason why a transfer of the powers and duties of the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act, to the Federal Security Administrator, should have any different legal or administrative effect than an ordinary succession of public officers. It is well settled that a change of personnel in an administrative agency or tribunal during the course of a hearing, or



at any time before the issuance of a final order on the hearing, does not invalidate the order. *Eastland Co. v. Federal Communications Commission*, C. A. D. C., 92 F. 2d 467, 470 (cert. den. 302 U. S. 735, 58 S. Ct. 120, 85 L. Ed. 568); *United States v. Reimer*, 2d Cir., 83 F. 2d 166, 167, 168; *State ex rel. American Telechronometer Co. v. Baker*, 164 Wash. 483, 2 P. 2d 1099, 1105; *Cocke v. MacLeod*, 85 Cal. App. 63, 258 P. 980, 981, 982.

The contention that the order should be held invalid on the ground that the Administrator did not read the record before the issuance of his order requires only a passing comment. There is no foundation for the contention except supposition, resting upon the fact that only six days intervened between the transfer of the duties of the Secretary of Agriculture to the Federal Security Administrator and the latter's promulgation of the regulation. The order of the Administrator, however, specifically recites that the "findings of fact, on the basis of which a definition and standard of identity is hereinafter fixed and established" have been made "upon consideration of the

evidence of record" and "of the Presiding Officer's report and objections thereto." The findings of fact of the Administrator also show some variances from those recommended by the trial examiner or presiding officer. An affirmative recitation of official regularity in an administrative order can hardly be overcome by mere implicational argument.

[*Ruling*]

As indicated above, the cause will be remanded to the Administrator for such finding as he is able and desires to make, as to the basis of his action in promulgating the regulation. Jurisdiction will be retained, so that if no such finding is made within thirty days hereafter, petitioners may apply for an order of final disposition, within ten days following. Respondent may similarly make a showing as to any supplementary finding or order made by him, and final disposition of the proceeding will thereafter be made.

*Cause Remanded to Federal Security Administrator.*

**TWIN CITY MILK PRODUCERS ASSOCIATION AND DES MOINES COOPERATIVE DAIRY v. HONORABLE PAUL McNUTT, FEDERAL SECURITY ADMINISTRATOR. AMERICAN DRY MILK INSTITUTE, INC., AND NATIONAL CO-OPERATIVE MILK PRODUCERS FEDERATION, INTERVENERS**

United States Circuit Court of Appeals for the Eighth Circuit. No. 505, Original. October Term, 1941. November 10, 1941. 123 F. 2d 396.

See *Twin City Milk Producers Association and Des Moines Cooperative Dairy v. McNutt et al.*, page 398.

A formal recitation that a regulation establishing a definition and standard of identity for a food was promulgated on the basis of the Administrator's judgment that it would promote honesty and fair dealing in the interest of consumers is not necessary, as a matter of statutory prescription, to give validity to the promulgating order. It is simply a judicial requirement, imposed as a convenience in a review proceeding.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Where an administrative order has failed to disclose the underlying basis for the official action, the courts, in order to avoid the necessity for summarily striking down the order, may permit a showing to be made as to the basis of the official action by amendatory or supplementary finding.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

Louis E. Hart for petitioners and interveners.

William W. Barron, Attorney, Department of Justice, for respondent.

Before WOODROUGH, JOHNSEN and VAN VALKENBURGH, Circuit Judges.



[*Approval of Regulation Previously  
 Withheld*]

JOHNSON, Circuit Judge: In a previous opinion, 122 F. 2d 564, we withheld approval of a regulation of the Federal Security Administrator, fixing a definition and standard of identity for "dried skim milk, powdered skim milk, skim milk powder," as a human food, because the Administrator's order promulgating the regulation did not affirmatively show that it was his judgment that his action would "promote honesty and fair dealing in the interest of consumers," which, under section 401 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1046, 21 U. S. C. § 341, was the sole basis of his authority to act.

Because of the field of public interest involved, we exercised our judicial discretion not to declare the regulation invalid summarily, for failure of the order to demonstrate that the necessary processes had been observed, as we might have done, but, with greater tolerance in the public interest, gave the Administrator an opportunity to disclose the basis of his action and to make such finding and showing with respect thereto as he might be able and desire to do; and we retained jurisdiction thereafter to make a final order of disposition.

[*Showing of Basis of Regulation Now Made*]

The Administrator has now filed, within the time limited in our order, a finding and showing that the regulation was promulgated on the basis of his judgment at the time that it would promote honesty and fair dealing in the interest of consumers, and that an amendment or supplement to the order of promulgation demonstrating such fact has been duly made and filed in the office of the Director of the Division of the Federal Register, the National Archives, under date of September 27, 1941, for publication in The Federal Register.

[*Question Before Court*]

The matter now comes before us on the Administrator's motion to affirm the original order on the basis of his amended or supplementary finding and showing. Petitioners and interveners have filed suggestions in opposition to the motion, renewing their argument that the original order is invalid for want of the necessary supportive finding as to the basis of the Administrator's action, and contending that the defect cannot properly be supplied by supplemen-

tary showing or amendment.

[*Court May Permit Nunc Pro Tunc Showing  
 of Basis of Regulation*]

The questions involved have been sufficiently considered in our previous opinion, and we adhere to the views there expressed. It may be added that the amendatory or supplementary finding which the Administrator has made does not in any way touch the language or provisions of the regulation itself; that the recitation as to the basis of the Administrator's action is collateral to the regulation proper; that such a formal recitation is not necessary, as a matter of statutory prescription, to give validity to the promulgating order; that it is simply a judicial requirement, imposed as a convenience in a review proceeding, to aid in satisfying legal conscience and in lightening judicial responsibility; that, in the absence of a controlling statutory prescription as to the scope or methods of the particular right of review, there is no limitation upon the general processes to which the courts may resort in satisfying themselves as to the propriety of the basis of administrative action, except such limitations as their own convenience and orderly functioning fittingly suggest; that, while the courts may thus refuse to approve and give further consideration to an administrative order which fails to show on its face that the action has been taken on the basis of the authority conferred by statute, they are not compelled thus to strike down such an order momentarily and summarily, and no person can claim any inherent right to demand that this be done; that where an administrative order has omitted to disclose the underlying basis of the official action, the courts, may properly, in their sound discretion, and where the general public interest is involved usually should, in order to avoid the necessity for summarily striking down the order, permit a showing to be made as to the basis of the official action, by amendatory or supplementary finding, and thereafter give consideration to the validity of the order in the light of this *nunc pro tunc* finding and showing.

As was declared in our previous opinion, "If official action actually rests upon a proper basis, and the recitations necessary to demonstrate this fact have simply been inadvertently omitted, there is no sound reason why this ought not to be permitted to be shown"; and, again, judicial responsibility to the public interest, where that



clearly is the dominant consideration involved, "will be more effectively served in this manner than by unnecessarily delaying administrative action and inviting repetitive litigation." 122 F. 2d at pages 567-568.

*[Order and Regulation Approved  
and Affirmed]*

In our previous opinion, we held that the regulation was in all other respects valid.

A satisfactory showing having now been made, by amended or supplementary finding, that the Administrator's order promulgating the regulation was made on the basis of his judgment at the time that it would promote honesty and fair dealing in the interest of consumers, it follows that the order and regulation should be, and they hereby are, approved and affirmed.

---

## QUAKER OATS CO. v. FEDERAL SECURITY ADMINISTRATOR

United States Circuit Court of Appeals for the Seventh Circuit. No. 7765.

June 26, 1942. 129 F. 2d 76.

Reversed, 318 U. S. 218. See page 419.

A petition was filed for a review of an order of the Administrator promulgating regulations establishing definitions and standards of identity for farina and enriched farina. Petitioner's participation in the hearings precluded it from invoking the issue of the sufficiency of the notice of the hearing.

Sections 401, 701 (e), Federal Food, Drug, and Cosmetic Act.

An administrative agency has only such authority in the administration of a statute as is expressly conferred, or as may be reasonably implied.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The Administrator's action in the interest of consumers is limited to the promotion of honesty and fair dealing in their behalf.

Section 401, Federal Food, Drug, and Cosmetic Act.

The promotion of honesty and fair dealing was intended by Congress to mean something other than the promotion of the consumers' health. Likewise, the promulgation of regulations under Section 401 was not authorized merely to avoid confusion on the part of consumers, or to educate the public as to dietary requirements.

Section 401, Federal Food, Drug, and Cosmetic Act.

While there may be some relevancy between the promotion of health and that of honesty and fair dealing, they are not synonymous terms.

Section 401, Federal Food, Drug, and Cosmetic Act.

There is little room for doubt that Congress used the words "honesty and fair dealing" in their ordinary sense.

Section 401, Federal Food, Drug, and Cosmetic Act.

Where a regulation prohibited the addition of vitamin D to "farina," and permitted the addition of that vitamin as an optional ingredient in "enriched farina," which was required to contain certain other vitamins, the findings with respect to the confusion of consumers were held to be speculative and conjectural.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.



**Federal Food, Drug, and Cosmetic Act**  
*Quaker Oats Co. v. Federal Security Administrator*

A product manufactured in accordance with the regulations would tend to increase rather than retard confusion; it was beyond the court's comprehension how the contention that confusion was likely to result from a product, such as petitioner's, which truthfully informed the consumer as to what he was buying, could be reconciled with the contention that a product sold as enriched farina, without any further description, would lessen or avoid confusion.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Another unreasonable and arbitrary result of the regulations was that petitioner would be precluded from adding vitamin D to its product, as it had done for many years, and, at the same time, would be permitted to add vitamin D as an optional ingredient in enriched farina, since no claim had been made of any relationship or co-action between vitamin D and the other ingredients required in enriched farina.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Courts will not substitute their judgment for that of an administrative agency on the wisdom or expediency of a determination within its jurisdiction. However, this rule was of no benefit to the Government, since the regulations, while purporting to be in the interest of consumers, did not promote honesty and fair dealing in their behalf.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

George I. Haight, Ward Ross, Wm. D. McKenzie, and James M. Best, all of Chicago, Ill., for petitioner.

Wendell Berge, Wm. W. Barron, and Louis B. Schwartz, all of Washington, D. C., for respondent.

Before SPARKS, MAJOR and MINTON, Circuit Judges.

*[Nature of Proceeding]*

MAJOR, Circuit Judge: This is a petition for review of respondent's order, entered May 26, 1941, promulgating regulations fixing and establishing definitions and standards of identity for "farina" and "enriched farina" and numerous related flour mill products.

*[Authority for Promulgation of Regulations]*

The authority relied upon by respondent is contained in Section 341, Title 21, U. S. C. A. Supp., entitled "Definitions and Standards for Food." (Section numbers used in this opinion refer to U. S. C. A.) The section, so far as here material, provides:

"Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: \* \* \*

*[Definitions of "Farina" and  
 "Enriched Farina"]*

The Administrator, after notice and hear-

ings participated in by members representing the pertinent industry, as well as consumer representatives, adopted findings of fact and concluded on the basis thereof that the regulations included in his order would promote honesty and fair dealing in the interest of consumers. Then follows the regulations fixing standards for a large number of flour products, as well as those involved in this proceeding, namely "farina" and "enriched farina." The former, designated as Reg. 15.130, defines farina as the food prepared by grinding and bolting clean wheat, other than durum wheat and red durum wheat, to a prescribed fineness, with bran coat and germ removed to the extent that the percentage of ash in the final product, calculated to a moisture free basis, does not exceed .6 percent. The latter, designated as Reg. 15.140, defines enriched farina as conforming to the standard fixed for farina, except that it contains prescribed minimum quantities of vitamin B<sub>1</sub>, riboflavin, nicotinic acid, and iron. Enriched farina, under the Administrator's standard, may contain as optional additional ingredients vitamin D, calcium, wheat germ, and disodium phosphate.



*Quaker Oats Co. v. Federal Security Administrator**[Petitioner's Contentions]*

While there is some disagreement as to the contested issues involved, we think they may be fairly summarized by petitioner's contention, disputed by respondent, that each of the regulations is unreasonable, that they do not promote honesty and fair dealing in the interest of consumers, and are not supported by substantial evidence. Furthermore, it is contended by petitioner that respondent was without authority to promulgate a regulation concerning enriched farina which had not been marketed theretofore, that the notice of the hearing did not purport to authorize the reception of evidence concerning such standard and that, as a matter of fact, evidence was not received pertinent thereto. It is also contended with respect to both standards that respondent, in administering the Act, has reached an unconstitutional result.

The basis upon which we think this case must be decided makes it unnecessary to enter into a discussion as to the character of notice given by respondent. It is sufficient to state that while petitioner's contention is not without merit, yet we are of the view that its participation in the hearings, both the original and the adjourned, were such as to preclude it from successfully invoking such issue. Likewise, we think it is unnecessary to enter into a discussion of petitioner's contention that the findings are without substantial support. For the purpose of this opinion (with certain exception noted hereinafter) we accept them.

*[Summary of Administrator's Findings]*

It is, therefore, sufficient to summarize the findings as made by respondent. A major portion of the hearings was devoted to the numerous grades of flour and only a minor portion to farina. As a consequence, most of the findings, strictly speaking, pertain to flour, which petitioner contends have no relevancy to farina and were, therefore, improperly included in the record. It must be conceded, we think, that there is such a close relationship between flour or, at any rate, some of the grades thereof, and farina, that it would be impractical, if not impossible, to consider the evidence and findings concerning the latter without giving consideration to the former.

Farina is a product obtained by grinding wheat and separating the bran coat and

germ of the grain from the endosperm. It consists essentially of endosperm in particles larger than permissible in flour, the size of the particles being the principal characteristic distinguishing the product from flour. In fact, it corresponds substantially to a fine grade of white flour known as "Patent Flour." It is used as a breakfast food, as an ingredient of macaroni products and extensively as a cereal food for children.

It was found that the removal of the bran coat and germ in the manufacture of flour and farina eliminates those parts of the wheat which are richest in vitamins and minerals. It was also found there exists a serious and widespread nutritional deficiency in children, as well as in adults, of vitamin B<sub>1</sub>, riboflavin, nicotinic acid, iron, calcium and vitamin D. These elements are available as synthetic compounds and are suitable for the enrichment of flour and farina. It was further found that vitamin D and calcium are used singly as enrichments of flour and farina, but consumer education has generally recommended dairy products as the most desirable source of the calcium and milk as the product most suitable for enrichment with vitamin D. It was found, however, that the addition of D and calcium as optional ingredients in enriched flour and enriched farina would be useful for those who consume insufficient dairy products.

It was found that manufacturers have recently placed on the market flours and farinas enriched with one or more of these nutritional elements.<sup>1</sup> The composition of these enriched products varies widely, so it is found, and unless a standard limiting the kinds and amounts of enrichment is adopted, the manufacturers' selection of nutritional elements is likely to lead to a great diversity of enrichment, both quantitative and qualitative. Such diversity would tend to confuse and mislead consumers as to the relative value and need of the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers. Indiscriminate enrichment with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of various vitamins and minerals, and would be likely to lead to the impression on the part of

vitamins have been added.

<sup>1</sup> This finding must refer largely to flours, as the record discloses only two farinas to which



consumers that a single article of food, so enriched, would meet all nutritional needs.

It was also found that, pending experience with the use of enriched flour and enriched farina, consumer education and understanding would be facilitated by restriction of enrichment with respect to the ingredients and, as to farina, the minimum amounts of such ingredients. The findings further recite that flour and farina enriched with vitamins and minerals have not acquired common or usual names, but that such products may be accurately designated as "enriched flour" and "enriched farina."

*[Administrator's Conclusion from Findings]*

Upon the basis of such findings, respondent concluded that it would "promote honesty and fair dealing in the interest of consumers" to adopt the standards of identity for farina and enriched farina embodied in the regulations in controversy. The record discloses certain other evidence not specifically covered by the findings, but not inconsistent therewith, to which we briefly refer.

*[Petitioner's Product]*

Petitioner has, since April, 1932, sold its product, labeled on the front panel of the package, "Quaker Farina Wheat Cereal, enriched with vitamin D," or "Quaker Farina enriched by the Sunshine Vitamin." On the back panel of the package is the following description:

"Contains 400 U. S. P. units of Vitamin D per ounce, supplied by approximately the addition of 1/5th of 1 per cent irradiated dry yeast."

During such period it has sold millions of packages annually and its product is of national reputation.

*[Functions and Efficacies of Vitamin D]*

Vitamin D functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones and teeth. It is recognized as especially beneficial in the infant and growing child as a preventive and therapy of rickets and the building of strong bones and teeth. It is also an essential vitamin for adults. There is medical testimony to the effect that of all the known vitamins, it is the one most deficient in normal diet and should, therefore, be supplied in foods which are consumed regularly by the great mass of population, particularly those in the low income groups. While the Administrator found that milk

was the most appropriate carrier for vitamin D, it is not disputed but that farina is also a proper carrier. Vitamin D in nature is found almost exclusively in sunshine and certain fish livers which are unavailable to humans in the normal diet. Therefore, as we understand, this vitamin is deficient in ordinary food products except when artificially supplied.

Thus, we have a situation where farina, with the addition of vitamin D, as manufactured and marketed by petitioner, is admittedly a wholesome and healthful product, (it is admitted in respondent's brief that vitamin D is a beneficial substance) and that it has been sold to millions of consumers, without deception, fraud or misrepresentation of any kind or character. As already pointed out, the regulations in question permit the manufacture and sale of plain farina and enriched farina. The regulation as to the former, in effect, prohibits petitioner from the sale of farina to which vitamin D has been added, as has long been its practice. The regulation as to the latter permits the use of vitamin D as an optional ingredient in connection with other vitamins, the use of which is mandatory.

*[Separate Treatment of Two Standards]*

Respondent criticizes, without merit we think, petitioner's treatment of the standards as separate and distinct. It is said they must be considered together, or, at any rate, with reference to each other. Such consideration, however, as we view the matter, furnishes little, if any, assistance to respondent's cause.

*[Authority To Promulgate Regulations]*

This brings us to what we regard as the heart of the controversy, embracing the issue as to respondent's authority to promulgate the regulations in dispute. Closely allied therewith is the question as to the reasonableness of the regulations, even if found to be within the authority conferred by the Act.

We assume there could be no dissent from the proposition that an administrative agency has only such authority in the administration of a Congressional enactment as is expressly conferred, or as may be reasonably implied. Prior to discussing the matter of respondent's authority, we again refer briefly to the findings of fact by which we are bound, if supported by substantial evidence. Sec. 371 (f) (3). As already



*Quaker Oats Co. v. Federal Security Administrator*

noted, we accept the findings with certain exceptions, one of which may, or may not, be a finding, viz., that the regulations in suit will promote honesty and fair dealing in the interest of consumers. We assume from respondent's arguments that this is regarded as a finding of fact, notwithstanding its being labeled as a conclusion and predicated upon the facts as found. Other than this labeled conclusion, the only reference in 92 findings to honesty and fair dealings is found in connection with the discussion as to the diversity of products of various manufacturers which, it is found, would "tend to confuse and mislead consumers \* \* \* and would impede rather than promote honesty and fair dealing in the interest of consumers." The conclusion that the regulations will promote honesty and fair dealing comes closer, in our judgment, to being one of law than of fact. If so, we are not bound to accept it. On the other hand, if it be considered as a finding of fact, we are of the view that it is without substantial support.

*[Promotion of Consumers' Interests as Basis for Regulations]*

All of the findings, labeled as such, as well as respondent's argument before this court, are bottomed upon the premise that the standards in controversy are authorized because they are in the interest of the consumer. As stated in his brief:

"The real issue, of course, is whether the requirements of the regulation are reasonably related to the promotion of consumers' interests. \* \* \*

A study of the record leaves no room for doubt but that the hearing revolved largely around consumer interest as it related to health. In referring to the ingredients of enriched farina, it is stated in respondent's brief: "They are essential to the health and well being of our nation." In support of the regulations it is also suggested that they will prevent confusion among consumers as to their nutritional needs. In this regard, respondent states:

"\* \* \* Indiscriminate enrichment with vitamins and minerals would tend to confuse and mislead consumers by giving rise to conflicting claims regarding the beneficial effects of various vitamins and minerals and would be likely to lead to the impression on the part of consumers that a single article of food so enriched would meet all nutritional needs. \* \* \*

It is still further suggested that the regulations will promote consumer understanding

of the relative value of enriched and natural foods.

As is shown by the statutory provision quoted heretofore, the Administrator is authorized to promulgate regulations fixing standards whenever, in his judgment, "such action will promote honesty and fair dealing in the interest of consumers." Thus, his action in the interest of consumers is expressly limited to the promotion of honesty and fair dealing in their behalf.

*[Congressional Intent]*

That the promotion of honesty and fair dealing was intended by Congress to mean something other than the promotion of the consumers' health is plainly ascertainable from a study of the Act. Likewise, it is clear that action was not authorized merely to avoid confusion on the part of consumers, nor to educate the public as to dietary requirements. If Congress had so intended, it would, no doubt, have employed the appropriate language. While there may be some relevancy between the promotion of health and that of honesty and fair dealing, they certainly are not synonymous terms. Injury to health does not necessarily follow from dishonesty and unfair dealing in food products, and neither does health improvement necessarily follow from honesty and fair dealing.

That Congress used the words "honesty and fair dealing" in their ordinary sense, we think there is little room to doubt. The general rule that legislative words must be so construed, is strengthened, so we think, by a reading of the Act which became a law June 25, 1938, entitled "Federal Food, Drug, and Cosmetic Act." It is divided into seven sub-chapters, including sub-chapter 4 relating to food, the one now under consideration. Under this sub-chapter, Section 341 defines the Administrator's authority for the fixing of standards. In addition to the language quoted heretofore from this section, it contains a clause, as follows:

"\* \* \* In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. \* \* \*

In other words, telling the consumer the truth as to optional ingredients is declared to be in the promotion of honesty and fair dealing. The law makers evidently did not contemplate the dietary requirements of consumers, the likelihood of confusion rela-



tive thereto, or their need for education as constituting a basis for the promotion of honesty and fair dealing.

Section 342 is entitled "Adulterated Food" and describes the conditions under which a food shall be deemed to be adulterated. It contains such designations as poisonous or deleterious to health, filthy, putrid, decomposed, substitution and concealment. Section 343 is entitled "Misbranded Food" and Paragraphs (a) to (k) inclusive describe such foods. Terms are employed such as false or misleading label, offering for sale under another name, imitation of another food, misleading container, and artificial flavoring. Paragraph (g) describes as misbranded a food represented as one for which a standard has been prescribed unless (1) it conforms to such definition and standard, and (2) its label bears the name specified in the standard and, insofar as required by the regulation, the name of any optional ingredients. It will thus be observed that the truth as to a food for which a standard has been fixed permits it to escape the indictment of being misbranded.

If defendant's contention be accepted that he has the authority to fix a standard as to the ingredients of a food which is truthfully labeled, then it would seem to follow that the statute indicts as misbranded that which, as a matter of fact, is correctly branded. This is the tortious result achieved by attempting to promote a dietary standard rather than honesty and fair dealing, as the statute requires. The result is all the more obnoxious in the instant situation where, as already pointed out, the consumer is adequately and truthfully informed as to petitioner's product which, in addition, is in no way deleterious to the health of the consumer.

Our discussion, designed to show that a standard food, although in the interest of the consumer, does not meet the test of honesty and fair dealing, is further strengthened by a study of sub-chapter V relating to drugs. As noted, this is a part of the same Act and enacted at the same time. While we make no attempt to construe this sub-chapter, a study of it readily discloses that the intention was to prohibit the sale of drugs under false, misleading and deceptive labels. In other words, it was sought to protect the consumer by requiring that he be truthfully informed as to the contents of the drug offered for sale. Illustrative

is Section 352 (d) which removes habit-forming drugs from the misbranded class where the label correctly bears the name and quantity of the ingredient, with the warning that it may be habit-forming. It seems unreasonable to think that Congress intended to apply the odious term "misbranded" to a food product correctly labeled and admittedly wholesome and beneficial, and permit drugs to escape such designation by the means of a truthful and honest label.

[*Confusion of Consumers as  
 Basis for Regulations*]

The findings and argument predicated upon the possibilities for confusion of consumers, in optional partial enrichment, carry little, if any, weight. There was no evidence in support of such possibilities and they are entirely speculative and conjectural. As was said in *Federal Trade Commission v. Raladam Company*, 283 U. S. 643, 653:

"\* \* \* All this was left without proof and remains, at best, a matter of conjecture. Something more substantial than that is required as a basis for the exercise of the authority of the Commission."

Looking at the realities of the situation, it is difficult to perceive how consumers' confusion, resulting from the truth as to the ingredients of a product, could support an action to promote honesty and fair dealing.

Furthermore, we should think that a product manufactured in accordance with the regulations in suit would tend to increase rather than retard confusion. This is especially true as to enriched farina. No such product has been sold heretofore under that designation. The manufacturer will be required only to label it "enriched farina" unless the option to add vitamin D is exercised, in which case such addition must be stated. How the ordinary consumer will be informed so as to avoid confusion as to what is meant by enriched farina, its contents, or the benefits to be expected from its use, is a mystery which we are not able to fathom. How the contention that confusion is likely to result from a product, such as petitioner's, which truthfully informs the consumer as to what he is buying, can be reconciled with the contention that a product sold as enriched farina, without any further description, will lessen or avoid confusion, is beyond our comprehension.



*Quaker Oats Co. v. Federal Security Administrator*

## [Unreasonableness of Vitamin D Requirements in Regulations]

Another unreasonable and, we think, arbitrary result of these regulations is that petitioner is precluded from adding vitamin D to its product, as it has done for many years and, at the same time, permitted to add vitamin D as an optional ingredient in enriched farina. We say it is unreasonable for the reason that no claim is made of any relationship or co-action between vitamin D and the other ingredients required in enriched farina. As a result, the consumer who is deficient in vitamin D only, as is often the case, must buy a product containing vitamins and ingredients which he does not need, or does not want, in order to obtain the benefit of vitamin D. Another unreasonable result, so we think, is that by the exclusion of vitamin D from petitioner's product, many people will be deprived of this admittedly essential vitamin. This result is none the less real by reason of the suggestion that milk is the most appropriate carrier of vitamin D, and that the majority of consumers (infants and children) who use petitioner's product are also large consumers of milk. There might be merit to this suggestion but for the fact that vitamin D is not a substantial ingredient of milk or any other natural food product in ordinary use. Thus, in order to obtain this essential vitamin in milk, it must be added thereto. Looking at the realities of the situation, we think this would mean that very few of the so-called low income group would receive sufficient vitamin D. Too many of them, no doubt, are without the necessary amount of milk, much less milk to which this vitamin has been added. So, as a final result, the regulations are responsible for a situation whereby a consumer is precluded from obtaining vitamin D alone in connection with farina; he may get it in connection with enriched farina at the option of the manufacturer, or he may get it with his milk, provided he possesses the foresight to see that it is added thereto.

## [Administrator's Authorities Not in Point]

Respondent relies strongly upon *United States v. Carolene Products Co.*, 304 U. S. 144, wherein the court sustained the validity of an act which prohibited the shipment in interstate commerce of skimmed milk compounded with any fat or oil other than milk fat, so as to resemble milk or cream. We think this case furnishes respondent's position little, if any, support. The court, in

commenting upon the Congressional hearings, on page 149, said:

"\* \* \* Both committees concluded, as the statute itself declares, that the use of filled milk as a substitute for pure milk is generally injurious to health and facilitates fraud on the public." and again, on page 151, it stated:

"Here the prohibition of the statute is inoperative unless the product is 'in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed.' \* \* \*"

As these quotations indicate, the court was considering legislation concerning a product which Congress concluded was injurious to health and a fraud upon the public. It was pointed out that the inferior product was indistinguishable from pure milk "thus making fraudulent distribution easy and protection of the consumer difficult." In the instant situation, however, there is nothing about the appearance of the product facilitating fraud upon the consumer. True, as the record discloses, plain farina, petitioner's farina and enriched farina are indistinguishable in appearance and taste. Petitioner's product, however, is in no sense a substitution, an imitation, or injurious to health. Therefore, if the condemning language of the *Carolene* case is applicable to petitioner's product, which we think it is not, it is also applicable to plain farina and enriched farina. So far as appearance and taste are concerned, there is no more likelihood of the consumer being deceived or confused as to petitioner's product than as to either of the others. Furthermore, the court in the *Carolene* case was dealing with the power of Congress, while here we are considering the authority which Congress has conferred upon the Administrator, and the reasonableness of his action.

*Hebe Company v. Shaw*, 248 U. S. 297, is also relied upon by respondent. This case was cited and relied upon in the *Carolene* case, (p. 148) and, we think, is likewise distinguishable. The element of fraudulent substitution was present in both cases.

## [Conclusion and Ruling]

We have not overlooked respondent's argument that courts will not substitute their judgment for that of an Administrative Agency on the wisdom or expediency of a determination within its jurisdiction. There is no occasion to cite or comment upon cases cited in support of this argument. We do not take issue—if fact, we



agree. The rule, however, is of no benefit to respondent in the instant situation because, as we have endeavoured to show, the regulations, while purporting to be in the interest of consumers, do not promote honesty and fair dealing in their behalf. On this statutory requirement, essential to respondent's authority to act, the record is

wholly deficient. In view of this situation, the action of respondent, in promulgating the regulations in controversy, was beyond his statutory authority. Such being the case, they must be set aside. It is so ordered.

---

**LAND O'LAKES CREAMERIES, INC., AND TWIN CITY  
 MILK PRODUCERS ASSOCIATION v. PAUL V. Mc-  
 NUTT, FEDERAL SECURITY ADMINISTRA-  
 TOR, NATIONAL COOPERATIVE MILK  
 PRODUCERS' FEDERATION AND  
 NATIONAL DAIRY UNION,  
 INTERVENERS**

United States Circuit Court of Appeals for the Eighth Circuit. No. 12,115,  
 January Term, 1943. January 21, 1943. 132 F. 2d 653.

A petition was filed to review an order of the Federal Security Administrator promulgating regulations establishing a definition and standard of identity for oleomargarine. Petitioners, engaged in the marketing of butter and milk, claimed that the order was invalid because it contravened Sections 403 (c) and 402 (b) (4) of the Act and because there was no substantial evidentiary support for the Administrator's determination that his order would promote honesty and fair dealing in the interest of consumers. The standard included, as optional ingredients, artificial coloring, sodium benzoate, Vitamin A, and the artificial flavoring diacetyl. The findings of fact upon which the Administrator's order was based were held to be sustained by substantial evidence.

Sections 401, 402 (b), 403 (c), 701 (f), Federal Food, Drug, and  
 Cosmetic Act.

Congress had not seen fit to limit the right of review to those directly affected by an order issued under Section 401, and the court, with some misgivings, would resolve its doubts with respect to its jurisdiction to review the Administrator's order in favor of the petitioners, marketers of a product which competed with the standardized product.

Sections 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

The judgment of the Administrator that his order would promote honesty and fair dealing in the interest of consumers could not be disturbed by the court. His right to make the judgment was equivalent to a discretionary power to act, which cannot be judicially reviewed.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

It was for the Administrator to resolve any conflict in the evidence, and to determine whether the optional ingredients should be permitted and whether in his judgment the standard, with the inclusion of the optional ingredients, would promote honesty and fair dealing in the interest of consumers. The Administrator's conclusions in such regards were neither arbitrary nor capricious and were, therefore, binding on the court.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Oleomargarine is a well-known food product with an identity of its own, and the Administrator had demonstrated that it was improbable that oleomargarine could, as a practical matter, successfully be passed off as butter.



*Land O'Lakes Creameries, Inc. et al. v. McNutt et al.*

Even if Section 403 (c) required that oleomargarine with the optional ingredients specified in the standard be labeled "imitation butter," the order could not be invalidated for that reason, since Section 403 (c) is independent of Section 401.

Sections 401, 403 (c), Federal Food, Drug, and Cosmetic Act.

The order established a definition of a food product and was not a license, to those who produced it, to violate any state or federal labeling requirements.

Sections 401, 403 (c), Federal Food, Drug, and Cosmetics Act.

The court could not rule that the use of the optional ingredients would make oleomargarine an adulterated food under Section 402 (b) (4), and at the same time be of the opinion that the standard was supported by valid findings of fact and sustained by substantial evidence. There was no conflict between the Administrator's order and Section 402 (b) (4).

Sections 401, 402 (b), 701 (f), Federal Food, Drug, and Cosmetic Act.

On the evidence adduced at the hearing before the Administrator, he had the power to make the order challenged; and whether the order was right or wrong was no concern of the court, for the court could not substitute its judgment for that of the Administrator.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Charles W. Wilson and W. E. Rumble (M. J. Doherty, John B. Gage, Donald W. Kane, Addison M. Parker, Addison M. Parker, Jr., Doherty, Rumble, Butler, Sullivan & Mitchell, and Gage, Hillix, Hodges & Cowherd were with them on the brief), for petitioners and interveners.

Louis B. Schwartz, Special Assistant to the Attorney General (Wendell Berge, Assistant Attorney General, James W. Knapp, Attorney, Department of Justice, and Signey Zagri, Attorney, Federal Security Agency, were with him on the brief), for respondent.

Phillip Tocker, attorney for National Cotton Council of America, as *amicus curiae* in support of respondent.

Before STONE, SANBORN, and RIDDICK, Circuit Judges.

## [Facts of Case]

SANBORN, Circuit Judge:

This is a petition to review an order of the respondent<sup>1</sup> made on June 5, 1941, promulgating regulations fixing and establishing a definition and standard of identity for oleomargarine under the Federal Food, Drug, and Cosmetic Act of 1938. (§ 401, 52 Stat. 1046, 21 U. S. C. A. § 341; § 701, 52 Stat. 1055, 21 U. S. C. A. § 371; Reorganization Act of 1939, 53 Stat. 561, 5 U. S. C. Supp. V, §§ 133 et seq., [see note, 5 U. S. C. A. following § 132, concerning §§ 133-133r]; Reorganization Plan No. IV,<sup>2</sup> 5 Fed. Reg. 2421, 54 Stat. 1234, 5 U. S. C. A. following § 133t; 54 Stat. 231, 5 U. S. C. A. § 133u.)

The petitioners are cooperative corpora-

tions engaged in the marketing of butter and milk. The interveners are similar organizations engaged in furthering the interests of the dairy and butter industry. Since the petitioners and the interveners seek the same relief, they will be collectively referred to as "petitioners."

The petitioners assert that the order is invalid because it contravenes §§ 403 (c) and 402 (b) (4) of the Federal Food, Drug, and Cosmetic Act [§§ 343 (c) and 342 (b) (4), 21 U. S. C. A.], which sections relate to the misbranding and to the adulteration of foods, and because there is no substantial evidentiary support for the respondent's determination that his order promotes honesty and fair dealing in the interest of consumers.

<sup>1</sup> The order was made by Watson B. Miller, as Acting Administrator of the Federal Security Agency, but, for convenience, will be referred to as though made by the respondent.

<sup>2</sup> Sec. 12 of Reorganization Plan No. IV trans-

ferred the administration of the Federal Food, Drug, and Cosmetic Act from the Secretary of Agriculture to the Federal Security Administrator.



By a motion to dismiss the petition and the intervening petitions, the respondent has challenged the right of the petitioners to maintain this proceeding.

*[Questions To Be Determined]*

The questions to be determined are, broadly, whether the petitioners can invoke a review by this court of the challenged order, and whether, if they are entitled to a review, the order is invalid for any of the reasons advanced by them.

*[Statutory Provisions Involved]*

Section 401 of the Federal Food, Drug, and Cosmetic Act provides that:

"Whenever in the judgment of the Secretary [Administrator] such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container \* \* \*.<sup>3</sup> In prescribing a definition and standard of identity for any food or class of foods in which optional ingredients are permitted, the Secretary [Administrator] shall, for the purpose of promoting honesty and fair dealing in the interests of consumers, designate the optional ingredients which shall be named on the label. \* \* \*"

Section 701 (e) of the Act provides that the Administrator "shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by" Section 401 of the Act; that at the hearing "any interested person" may be heard in person or by his representative; that, as soon as practicable after completion of the hearing, the Administrator shall by order make public his action or his decision not to act; and that his order shall be based only on substantial evidence of record at the hearing and shall set forth the detailed findings of fact on which the order is based.

Subsection (f) of Section 701 of the Act provides that "in a case of actual controversy as to the validity of any order" under subsection (e) of Section 701, "any person who will be adversely affected by such order if placed in effect" may, within ninety days after its issuance, file a petition with the Circuit Court of Appeals of the United States for the Circuit in which he resides or has his principal place of busi-

ness "for a judicial review of such order;" that "the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently;" that "if the order of the Secretary [Administrator] refuses to issue, amend, or repeal a regulation and such order is not in accordance with law, the court shall by its judgment order the Secretary [Administrator] to take action, with respect to such regulation, in accordance with law;" and that "the findings of the Secretary [Administrator] as to the facts, if supported by substantial evidence, shall be conclusive." Subsection (f) of Section 701 also provides that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

*[Order and Standard]*

The challenged order establishing a definition and standard of identity for oleomargarine was made after a hearing held upon due notice. The order contains detailed findings of fact and a determination that the standard "would promote honesty and fair dealing in the interest of consumers." The standard of identity established by the order states that oleomargarine is a plastic food prepared from animal fat or vegetable fat or oil, or a combination of both animal and vegetable fat, which is intimately mixed with milk ingredients. The standard includes as optional ingredients:

"(5) Artificial coloring.

"(6) Sodium benzoate, or benzoic acid, or a combination of these, in a quantity not to exceed 0.1 percent of the weight of the finished product.

"(7) Vitamin A \* \* \* in such quantity that the finished oleomargarine contains not less than 9,000 United States Pharmacopoeia Units of Vitamin A per pound.

"(8) The artificial flavoring diacetyl added as such, or as starter distillate, or produced during the preparation of the product as a result of the addition of citric acids or harmless citrates."

The standard requires that if artificial coloring or diacetyl, or benzoate of soda, or Vitamin A is used in oleomargarine, the label must disclose the fact.

*[Findings of Fact]*

The findings of fact of the respondent show that diacetyl is an artificial flavoring produced in oleomargarine by the action of

<sup>3</sup> Certain foods, including butter, are not subject to the authority granted the Administrator

to establish definitions and standards of identity.



certain harmless bacterial starters, and that diacetyl is also added to oleomargarine as an additional ingredient to enhance the flavor of the finished product; that some consumers use oleomargarine for the same purposes as butter, and that the addition of 9,000 Units of Vitamin A per pound will give a Vitamin A content comparable to that of butter; that present conditions of retail distribution of oleomargarine do not afford adequate refrigeration for the product, and that sodium benzoate or benzoic acid, or both, are sometimes added to aid in retarding deterioration; and that butter, salt and artificial flavoring are sometimes used in the preparation of oleomargarine.

*[Findings Sustained by Evidence]*

Our examination of the evidence adduced at the hearing before the respondent convinces us that all of the findings of fact upon which the respondent's order is based are sustained by substantial evidence. The evidence at the hearing was directed at ascertaining what ingredients had been and were being used in the preparation of oleomargarine and what ingredients consumers understood were contained in that product. The testimony amounted to a quantitative and qualitative analysis of that food product. The only substantial dispute which arose during the hearing was as to the propriety of the use of diacetyl as an optional ingredient of oleomargarine. Henry A. Lepper, a chemist in the Food and Drug Administration of the Federal Security Agency, who, for many years, had been concerned with regulatory problems in the enforcement of the Federal food laws and in the analysis of foods, testified, in substance, that in his opinion the permitted use of diacetyl in the manufacture of oleomargarine was not in the interest of honesty and fair dealing, because diacetyl produces or enhances the butter flavor and would lead uninformed consumers to believe that there were substantial quantities of butter present in oleomargarine. Mr. Lepper had previously, at the hearing, testified that the standard of identity proposed by the respondent in his notice of hearing "would promote honesty and fair dealing in the interests of consumers because it would fulfill the consumers' conception of what the product should be, and would assure the consumer a minimum of fat commensurate with that understanding;" and that "it would also assure the consumer that dairy products in the nature of skim milk or reconstituted milk had been used

in its preparation, because the consumer generally believes that to be a fact." The proposed standard of identity to which Mr. Lepper was then referring was substantially similar to that finally adopted by the respondent, except that diacetyl was not an optional ingredient in the standard originally proposed, nor was benzoate of soda or benzoic acid. Mr. Lepper testified that bacterial starters are generally used to promote the growth of lactic acid bacteria in the milk ingredient; that in that way the best flavor is developed, a "flavor that is associated with dairy products," and that consumer understanding is that dairy products are present in oleomargarine, and this flavor is developed by the bacteria that ordinarily develop flavor in dairy products. Mr. Lepper conceded in his testimony that, without the addition of diacetyl, oleomargarine might have the same butter flavor, depending upon how rich the milk ingredient used was in the properties which give flavor. It was clearly Mr. Lepper's opinion, however, that diacetyl, if added as an ingredient, would be used to enhance the butter flavor of oleomargarine, and would or might create the impression that substantial quantities of butter had been incorporated, and would therefore make the product appear to be better or of greater value than it was; and that he did not believe that "fundamental deceptions, arising out of appearance or flavor, were correctable by any form of label statement." There was testimony on behalf of the oleomargarine industry that the only purpose of the addition of diacetyl was to overcome the deficiency of citrates in some of the milk ingredient used in the manufacture of oleomargarine and to give to the consumer a product which would, so far as possible, have a uniform flavor.

A witness who testified in the interests of the consumers of oleomargarine, expressed the opinion that a preservative such as benzoate of soda or benzoic acid might be used to conceal an unsanitary or inferior product. There was other evidence that such a product could not be improved by the addition of these preservatives, and that the only purpose that they served was to enable the consumer to obtain the product in substantially the same condition as when it left the producer's hands.

*[Exceptions Filed by Federation]*

None of the petitioners appeared at the hearing except the National Cooperative



Milk Producers' Federation, which, perhaps, may be regarded as having represented the interests of the other petitioners and of the butter industry generally. The Federation introduced no evidence, took no part in the examination of witnesses produced by the respondent and by the oleomargarine industry, made no suggestions of any kind at the hearing as to what would constitute a proper standard of identity for oleomargarine, and was entirely inactive until the hearing was over, when it filed exceptions (with a supporting brief) to the findings and order which the respondent after the hearing and on April 14, 1941, gave notice that he proposed to make and which he finally did make on June 5, 1941. The exceptions were directed against the inclusion of sodium benzoate, Vitamin A, diacetyl (starter distillate, citric acid or citrates) as optional ingredients, and against the respondent's determination that his order would promote honesty and fair dealing in the interest of consumers. The Federation in its brief, submitted with its exceptions, asserted that, "since the product, oleomargarine lends itself to fraud and deception by virtue of the very fact that the consumer has come to associate dairy products with its flavor, nothing which permits this substitute product to more nearly simulate the dairy product butter will do other, in our judgment, than aggravate its fraudulent and deceptive sale." The National Dairy Union also filed with the respondent exceptions to the proposed order, with supporting brief.

#### [Contentions of Respondent]

The respondent contends that the petitioners are not persons "adversely affected" by the standard of identity for oleomargarine, and that they have no "actual controversy" within the means of § 701 (f) (1) of the Act. The respondent points out that the provisions of his order operate solely upon the oleomargarine industry; that it does not exempt that industry from compliance with all state and federal laws affecting its product; that it confers upon the industry no privileges which did not exist prior to the adoption of the standard, and that the order cannot adversely affect the butter industry or those engaged in it, since their competitive position is not affected by the order. The respondent also contends that, in so far as the petitioners assert that the regulation fixing the standard is not in the interest of consumers,

they urge a grievance which is not their own. The respondent relies upon *Interstate Commerce Commission v. Chicago, R. I. & Pac. Ry. Co.*, 218 U. S. 88, 109; *L. Singer & Sons v. Union Pacific R. Co.*, 311 U. S. 295, 304, 306; *Perkins v. Lukens Steel Co.*, 310 U. S. 113, 125; *Tennessee Electric Power Co. v. Tennessee Valley Authority*, 306 U. S. 118, 139-140; *Alabama Power Co. v. Ickes*, 302 U. S. 464, 480-485; *Moffat Tunnel League v. United States*, 289 U. S. 113, 119; *Alexander Sprunt & Son, Inc. v. United States*, 281 U. S. 249, 255-256; *Edward Hines Yellow Pine Trustees v. United States*, 263 U. S. 143, 148-149; *Commonwealth of Massachusetts v. Mellon*, 262 U. S. 447, 488; *Fairchild v. Hughes*, 258 U. S. 126, 129; and other cases. It is the respondent's opinion that Congress intended that the right to a review of such an order as the one under consideration should be confined to persons directly affected by the order, namely, the members of the industry concerned, consumers directly affected, and possibly suppliers of ingredients which were excluded by the standard set up. (See *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 7 Cir., 120 F. 2d 258, 259-266.)

#### [Contentions of Petitioners]

The petitioners argue, in effect, that the order licenses the oleomargarine industry to engage in unfair and unlawful competition with them, that they have a large stake in the butter industry, and that they are, therefore, persons "adversely affected" by the order. They rely upon such cases as *Alton Railroad Co. v. United States*, 315 U. S. 15, 18-20; *Federal Communications Commission v. Sanders Brothers Radio Station*, 309 U. S. 470, 476-477, and 642; *Claiborne-Annapolis Ferry Co. v. United States*, 285 U. S. 382, 390. The petitioners also contend that they are "interested persons" who were represented at the hearing before the respondent, and are to be regarded as parties to that proceeding against whom an adverse order has been entered.

The producers of butter and the producers of oleomargarine have been for many years competing in the same field, if not exactly upon the same economic plane. The petitioners believe that the order of the respondent, which standardizes the use of optional ingredients in oleomargarine which they think it should not be permitted to contain, impairs the petitioners' competitive position, adversely affects them, and is invalid.



*[Controversy Is Actual Controversy]*

It seems to us that the controversy between the petitioners and the respondent is an actual controversy over the lawfulness of the respondent's order. Congress did not see fit to limit the right of review to those directly affected by such an order—as it might readily have done—and the case of *Federal Communications Commission v. Sanders Brothers Radio Station*, 309 U. S. 470, 476-477, lends substantial support to the petitioners' argument respecting their right to a review.

*[Jurisdiction To Review Order]*

We have, with some misgivings, concluded to resolve our doubts with respect to our jurisdiction to review the respondent's order in favor of the petitioners.

*[Determination that Order Will Promote Honesty and Fair Dealing]*

The judgment or determination of the respondent that the order will promote honesty and fair dealing in the interest of consumers cannot, we think, be disturbed by this Court. "His right to make the judgment is, of course, equivalent to a discretionary power to act, which cannot be judicially reviewed. *United States v. George S. Bush & Co., Inc.*, 310 U. S. 371, 380." *Twin City Milk Producers Ass'n v. McNutt*, 8 Cir., 122 F. 2d 564, 566. (Compare, *Quaker Oats Co. v. Federal Security Administrator*, 7 Cir., 129 F. 2d 76, 81, certiorari granted, 317 U. S. —, 63 S. Ct. 158.) And, if the respondent's determination in that regard were subject to review by this Court, we would still be of the opinion that it would have to stand. We have already shown that the standard of identity adopted was substantially the standard of identity proposed in the respondent's notice of hearing, with the exception of the optional ingredients diacetyl and benzoate of soda; that there was substantial evidence that the standard of identity proposed would promote honesty and fair dealing in the interest of consumers; and that the only real disagreement between the witnesses at the hearing was as to the propriety of the use of diacetyl as an optional ingredient. It was for the respondent to resolve this conflict in the evidence, and to determine whether diacetyl should be an optional ingredient and whether in his judgment the standard of identity with the inclusion of this ingredient would promote honesty and fair dealing in the interest of consumers. His conclu-

sions in these regards are, we think, neither arbitrary nor capricious, and are, therefore, binding upon this Court.

*[Question for Consideration]*

That leaves for consideration the questions of whether the order violates the misbranding provision and the adulteration provision of the Act.

*[Order Not Violative of Statutory Provision Concerning Imitations]*

Section 403 (c) of the Act [21 U. S. C. A. § 343 (c)] provides that a food shall be deemed misbranded "if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated."

The petitioners, in their brief, assert as follows:

"It is quite obvious that the testimony upon which the respondent's order is supposedly based discloses that these various permitted optional ingredients are used for the sole purpose of simulating the genuine product butter. It is the duty under the law of respondent to require manufacturers of oleomargarine if they are to use these ingredients in their product to label their product in accordance with the plain mandate of Congress, namely, with the word 'imitation' together with the name of the product (butter) imitated. This the respondent did not do. His order is repugnant to the provisions of Sec. 403 (c) of the Act and consequently void."

The answer of the respondent is that oleomargarine containing the optional ingredients referred to in the order, is not "an imitation" of butter within the meaning of § 403 (c); that the mere resemblance or similarity of one food to another is insufficient to make one an "imitation" of the other; and that what § 403 (c) is directed at is preventing a spurious food being passed off as genuine. The respondent also contends that, even if some oleomargarine conforming to the standard of identity might be sold under circumstances which might possibly make it an "imitation" of butter under § 403 (c), that fact would not vitiate the standard, since the provisions of § 401, relating to the establishment of standards of identity, and the provisions of § 403 (c) requiring that imitations of foods be labeled as such, are not conflicting and are independent of each other.

Oleomargarine is a well known food



product with an identity of its own, and there is nothing in the record before us, with the possible exception of the expert opinion expressed by Mr. Lepper (with which the respondent did not agree) to indicate that oleomargarine has been, or is likely to be, passed off as butter; that it is, or is likely to be, used as a deceptive imitation of butter; or that labeling requirements will not effectually protect consumers against fraud. The respondent, we think, has convincingly demonstrated in his brief that, in view of federal and state restrictions imposed upon the sale of oleomargarine, it is improbable that it could, as a practical matter, be successfully passed off as butter. But if § 403 (c) requires that oleomargarine containing the optional ingredients specified in the standard be labeled "imitation butter," it is our opinion that the respondent's order cannot be invalidated for that reason, because we regard § 403 (c) as independent of § 401. If § 403 (c) imposed the duty upon the respondent to require all oleomargarine containing the ingredients designated in the standard as optional, to be labeled "imitation butter," that duty existed both before and after the order was made, since the order does not impair, or purport to impair, the effectiveness of § 403 (c). The order establishes a definition of a food product, and is not a license, to those who produce it, to violate any state or federal labeling requirements.

*[Order Not Violative of Statutory Provision Concerning Adulteration]*

Sec. 402 (b) (4) of the Act [21 U. S. C. A. § 342 (b) (4)] provides that a food shall be deemed to be adulterated "if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." In order to determine whether anything has been added to a food which makes it appear "better or of greater value than it is," it is necessary to know first of all what the food is. The purpose of the respondent's order was to ascertain the ingredients of oleomargarine and to define and identify it. Under the

definition which he adopted, oleomargarine is a food which contains the ingredients and optional ingredients specified in the definition and standard of identity. It is not conceivable to us that we could rule that the use of one or more of the optional ingredients would make oleomargarine an adulterated food, and at the same time be of the opinion that the standard of identity established by the order was supported by valid findings of fact and sustained by substantial evidence. We think there is no conflict between the order of the respondent and § 402 (b) (4) of the Act.

*[Petitioner Should Have Objected to Optional Ingredients at Administrative Hearings]*

What the petitioners are really objecting to is the inclusion by the respondent, in the standard of identity established, of optional ingredients which they contend should have been excluded by him. They should have made their fight for these exclusions before the respondent, and not before this Court. Upon the evidence adduced at the hearing, we are convinced that the respondent had the power to make the order which is challenged. Whether the order is right or wrong is no concern of this Court, for it cannot substitute its judgment for that of the respondent. See and compare, *Gray v. Powell*, 314 U. S. 402, 412; *Pittsburgh Plate Glass Co. v. National Labor Relations Board*, 8 Cir., 113 F. 2d 698, 701, affirmed 313 U. S. 146; *Railroad Commission of Texas v. Rowan & Nichols Oil Co.*, 310 U. S. 573, 580-581; *National Labor Relations Board v. Waterman Steamship Co.*, 309 U. S. 206, 226; *National Labor Relations Board v. Nevada Consolidated Copper Corp.*, 316 U. S. 105; *Eagle-Picher Mining & Smelting Co. v. National Labor Relations Board*, 8 Cir., 119 F. 2d 903, 907; *National Labor Relations Board v. Bradford Dyeing Ass'n*, 310 U. S. 318, 342.

*[Petitions Dismissed]*

The motion of the respondent to dismiss the original and intervening petitions is denied.

*[Order Establishing Standard Affirmed]*

The order under review is affirmed.



**FEDERAL SECURITY ADMINISTRATOR v. QUAKER  
OATS COMPANY**

United States Supreme Court. No. 424, October Term, 1942. March 1,  
1943. 318 U. S. 218. 63 S. Ct. 589.

Reversing 129 F. 2d 76. See page 405.

A petition was filed to review an order of the Federal Security Administrator promulgating regulations establishing definitions and standards of identity for milled wheat products. The regulations excluded Vitamin D from the defined standard of "farina" and permitted it only as an optional ingredient in "enriched farina," which was required to contain other vitamins. The Act does not contemplate that the courts should substitute their judgment for that of the Administrator.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

While under Section 701 (f) the Administrator's regulations must be supported by findings based upon "substantial evidence," the findings are conclusive if based on substantial evidence.

Sections 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

The court has repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body. Such considerations are especially appropriate where the review is of regulations of general application adopted by an administrative agency under its rule-making power.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Section 401 calls for the exercise of the "judgment of the Administrator." That judgment, if based on substantial evidence of record, and if within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Where regulations excluded Vitamin D from "farina" and permitted it in "enriched farina," which was required to contain other vitamins, taking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values, there was sufficient evidence of "rational probative force" to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The exercise of the administrative rule-making power necessarily looks to the future.

Section 401, Federal Food, Drug, and Cosmetic Act.

Both the text and legislative history of the Act plainly show that its purpose was not confined to a requirement of truthful and informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained," and to require informative labeling only where no such standard has been promulgated, where the food does not purport to comply with a standard, or where the regulations permit optional ingredients and require their mention on the label.

Section 401, Federal Food, Drug, and Cosmetic Act.



**Federal Food, Drug, and Cosmetic Act**  
*Federal Security Administrator v. Quaker Oats Co.*

The provisions for standards of identity reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other. It cannot be said that such a standard, designed to eliminate a source of confusion to purchasers, will not "promote honesty and fair dealing" within the meaning of the statute.

Section 401, Federal Food, Drug, and Cosmetic Act.

Charles Fahy, Solicitor General; Wendell Berge, Assistant Attorney General; Louis B. Schwartz, Irwin L. Langbein, Richard S. Salant, Attorneys; Jack Tate, General Counsel, Federal Security Agency; P. D. Cronin, Assistant General Counsel, Federal Security Agency; Edward B. Williams, Attorney, Federal Security Agency; for petitioner.

George I. Haight, William D. McKenzie, Chicago, Ill.; James M. Best, Ward Ross, Merrill E. Olsen; for respondent.

[*Question Before Court*]

Mr. Chief Justice STONE: The Federal Security Administrator, acting under §§ 401 and 701 (e), of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, 1046, 1055, (21 U. S. C. §§ 341, 371), promulgated regulations establishing "standards of identity" for various milled wheat products, excluding vitamin D from the defined standard of "farina" and permitting it only in "enriched farina," which was required to contain vitamin B<sub>1</sub>, riboflavin, nicotinic acid and iron. The question is whether the regulations are valid as applied to respondent. The answer turns upon (a) whether there is substantial evidence in support of the Administrator's finding that indiscriminate enrichment of farina with vitamin and mineral contents would tend to confuse and mislead consumers; (b) if so, whether, upon such a finding, the Administrator has statutory authority to adopt a standard of identity, which excludes a disclosed non-deleterious ingredient, in order to promote honesty and fair dealing in the interest of consumers; and (c) whether the Administrator's treatment, by the challenged regulations, of the use of vitamin D as an ingredient of a product sold as "farina" is within his statutory authority to prescribe "a reasonable definition and standard of identity."

[*Statutory Provisions*]

Section 401 of the Act provides that "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations

fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity. . . . In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label." By § 701 (e) the Administrator, on his own initiative or upon application of any interested industry or a substantial part of it, is required to "hold a public hearing upon a proposal to issue, amend or repeal any regulation contemplated by" § 401. At the hearing "any interested person may be heard." The Administrator is required to promulgate by order any regulation he may issue, to "base his order only on substantial evidence of record at the hearing," and to "set forth as part of his order detailed findings of fact on which the order is based."<sup>1</sup>

Any food which "purports to be or is represented as a food for which a definition and standard of identity has been prescribed" pursuant to § 401 is declared by § 403 (g) to be misbranded "unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients . . . present in such food." The shipment in interstate commerce of "misbranded" food is made a penal offense by §§ 301 and 303. "In a case of actual controversy as to the validity" of an order issuing regulations

<sup>1</sup> As enacted, the Act vested the foregoing powers in the Secretary of Agriculture. By §§ 12 and 13 of Reorganization Plan No. IV, 54 Stat. 1234, 1237, approved April 11, 1940, the Federal Food and Drug Administration and

all functions of the Secretary of Agriculture relating thereto were transferred to the Federal Security Agency and the Federal Security Administrator.



*Federal Security Administrator v. Quaker Oats Co.*

under § 401 any person "adversely affected" by it may secure its review on appeal to the Circuit Court of Appeals for the circuit of his residence or principal place of business. On such review the findings of the Administrator "as to the facts, if supported by substantial evidence, shall be conclusive." § 701 (f) (1), (f) (3).

*[Farina Regulations]*

After due notice<sup>2</sup> and a hearing in which respondent participated, the Administrator by order promulgated regulations establishing definitions and standards of identity for sixteen milled wheat products, including "farina" and "enriched farina." Regulation 15.130 defined "farina" as a food prepared by grinding and bolting cleaned wheat, other than certain specified kinds, to a prescribed fineness with the bran coat and germ of the wheat berry removed to a prescribed extent. The regulation made no provision for the addition of any ingredients to "farina." Regulation 15.140 defined "enriched farina" as conforming to the regulation defining "farina," but with added prescribed minimum quantities of vitamin B<sub>1</sub>, riboflavin,<sup>3</sup> nicotinic acid (or nicotinic acid amide) and iron. The regulation also provided that minimum quantities of vitamin D, calcium, wheat germ or disodium phosphate might be added as optional ingredients of "enriched farina," and required that ingredients so added be specified on the label. In support of the regulations the Administrator found that "unless a standard" for milled wheat products "is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of the need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers."

*[Order Set Aside by Court of Appeals]*

On respondent's appeal from this order the Court of Appeals for the Seventh Circuit set it aside, 129 F. 2d 76, holding that the regulations did not conform to the statutory standards of reasonableness, that the Administrator's findings as to probable consumer confusion in the absence of the prescribed standards of identity were without support in the evidence and were "entirely speculative and conjectural," and that in any case such a finding would not justify the conclusion that the regulations would "promote honesty and fair dealing in the interest of consumers." We granted certiorari, 317 U. S. 616, because of the importance of the questions involved to the administration of the Food, Drug and Cosmetic Act.

*[Product Involved]*

Respondent, The Quaker Oats Company, has for the past ten years manufactured and marketed a wheat product commonly used as a cereal food, consisting of farina as defined by the Administrator's regulation, but with vitamin D added. Respondent distributes this product in packages labeled "Quaker Farina Wheat Cereal Enriched with Vitamin D," or "Quaker Farina Enriched by the Sunshine Vitamin." The packages also bear the label "Contents 400 U. S. P. units of Vitamin D per ounce, supplied by approximately the addition of 1/5 of 1 percent irradiated dry yeast."

*[Effect of Standards Upon Respondent's Product]*

Respondent asserts, and the Government agrees, that the Act as supplemented by the Administrator's standards will prevent the marketing of its product as "farina" since, by reason of the presence of vitamin D as an ingredient, it does not conform to the standard of identity prescribed for "farina," and that respondent cannot market its product as "enriched farina" unless it adds the prescribed minimum quantities of vitamin B<sub>1</sub>, riboflavin, nicotinic acid and iron. Respondent challenges the validity of the regulations on the grounds sustained below and others so closely related to them as not to require separate consideration.

<sup>2</sup> Respondent contended in the court below that the notice was inadequate. It appears to have abandoned that contention here, but in any event we think that it is without merit in view of respondent's participation in the original hearing, and in view of the publication of notice of a reconvened hearing devoted solely

to the "propriety of the addition of vitamins and minerals to . . . (I) farina . . .".

<sup>3</sup> The effective date of the riboflavin requirement has been postponed until April 20, 1943, because it appeared that the available supply was inadequate. 7 Fed. Reg. 3055.



*[Vitamins Removed from Milled Wheat]*

As appears from the evidence and the findings, the products of milled wheat are among the principal items of the American diet, particularly among low income groups.<sup>4</sup> Farina, which is a highly refined wheat product resembling flour but with larger particles, is used in macaroni, as a breakfast food, and extensively as a cereal food for children. It is in many cases the only cereal consumed by them during a period of their growth. Both farina and flour are manufactured by grinding the whole wheat and discarding its bran coat and germ. This process removes from the milled product that part of the wheat which is richest in vitamins and minerals, particularly vitamin B<sub>1</sub>, riboflavin, nicotinic acid and iron, valuable food elements which are often lacking in the diet of low income groups. In their diet, especially in the case of children, there is also frequently a deficiency of calcium and vitamin D, which are elements not present in wheat in significant quantities. Vitamin D, whose chief dietary value is as an aid to the metabolism of calcium, is developed in the body by exposure to sunlight. It is derived principally from cod liver and other fish oils. Milk is the most satisfactory source of calcium in digestible form, and milk enriched by vitamin D is now on the market.

*[Enrichment of Milled Wheat]*

In recent years millers of wheat have placed on the market flours and farinas which have been enriched by the addition of various vitamins and minerals. The composition of these enriched products varies widely.<sup>5</sup> There was testimony of weight before the Administrator, principally by expert nutritionists, that such products, because of the variety and combination of added ingredients, are widely variable in nutritional value; and that consumers generally lack knowledge of the relative value

of such ingredients and combinations of them.

*[Confusion of Consumers]*

These witnesses also testified, as did representatives of consumer organizations which had made special studies of the problems of food standardization, that the number, variety and varying combinations of the added ingredients tend to confuse the large number of consumers who desire to purchase vitamin-enriched wheat food products but who lack the knowledge essential to discriminating purchase of them; that because of this lack of knowledge and discrimination they are subject to exploitation by the sale of foods described as "enriched," but of whose inferior or unsuitable quality they are not informed. Accordingly a large number of witnesses recommended the adoption of definitions and standards for "enriched" wheat products which would ensure fairly complete satisfaction of dietary needs, and a somewhat lesser number recommended the disallowance, as optional ingredients in the standards for unenriched wheat products, of individual vitamins and minerals whose addition would suggest to consumers an adequacy for dietary needs not in fact supplied.

The court below characterized this evidence as speculative and conjectural, and held that because there was no evidence that respondent's product had in fact confused or misled anyone, the Administrator's finding as to consumer confusion was without substantial support in the evidence. It thought that, if anything, consumer confusion was more likely to be created, and the interest of consumers harmed, by the sale of farinas conforming to the standard for "enriched farina," whose labels were not required to disclose their ingredients, than by the sale of respondent's product under an accurate and informative label such as that respondent was using.

<sup>4</sup> One witness at the hearing referred to estimates that over 95% of human consumption of wheat products is in the form of white flour.

<sup>5</sup> The report of the officer presiding at the hearing enumerates the following varieties disclosed by the testimony:

"Flours, phosphated flours, and self-rising flours—

1. One with added vitamin D;
2. One with added calcium;
3. One with added vitamin B<sub>1</sub>, nicotinic acid, and calcium [produced by some 23 mills];
4. One with added vitamin B<sub>1</sub>, calcium, and iron;

5. One containing wheat germ oil, said to furnish vitamin B<sub>1</sub>, vitamin E and riboflavin;

6. One 'long extraction' flour containing vitamin B<sub>1</sub>, riboflavin, calcium and iron."

"Farinas—

7. One with added vitamin D;

8. One with added vitamin B<sub>1</sub>, calcium and iron."

The labels used, and advertising claims made, for those products were not in the record. However, there was testimony that certain of these were sold under such names as "Sunfed," "Vitawhite," "Holwhite."



[Court Should Not Substitute Judgment  
for That of Administrator]

The Act does not contemplate that courts should thus substitute their own judgment for that of the Administrator. As passed by the House it appears to have provided for a judicial review in which the court could take additional evidence, weigh the evidence, and direct the Administrator "to take such further action as justice may require." H. R. Rep. No. 2139, 75th Cong., 3d Sess., pp. 11-12. But before enactment, the Conference Committee substituted for these provisions these which became § 701 (f) of the Act. While under that section the Administrator's regulations must be supported by findings based upon "substantial evidence" adduced at the hearing, the Administrator's findings as to the facts if based on substantial evidence are conclusive. In explaining these changes the chairman of the House conferees stated on the floor of the House that "there is no purpose that the court shall exercise the functions that belong to the executive or the legislative branches." 83 Cong. Rec., p. 9096. See also H. R. Rep. No. 2716, 75th Cong. Rec., 3d Sess., p. 25. Compare *Federal Radio Commission v. General Electric Co.*, 281 U. S. 464.

The review provisions were patterned after those by which Congress has provided for the review of "quasi-judicial" orders of the Federal Trade Commission and other agencies, which we have many times had occasion to construe.<sup>6</sup> Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body. *Federal Trade Comm'n v. Education Society*, 302 U. S. 112, 117; *Gray v. Powell*, 314 U. S. 402, 412; *Labor Board v. Link Belt Co.*, 311 U. S. 584, 597; see *Federal Communications Commission v. Pottsville Broadcasting Co.*, 309 U. S. 134, 141, 144. These considerations are especially appropriate where the review is of regulations of general application adopted by an administrative agency under its rule-making power in carrying out the policy of a statute with whose enforcement it is charged. Compare *Houston v. St. Louis Independent Packing Co.*, 249 U. S. 479, 487; *Opp Cotton Mills v. Administrator*, 312 U. S. 126, 156.

<sup>6</sup> The provision adopted by the Conference Committee is one which was proposed as an amendment from the floor of the House by Mr. Mapes, a minority member of the House Committee and one of the House conferees. In proposing it he said that it was "the same as the court review section in the Federal Trade

Section 401 calls for the exercise of the "judgment of the Administrator." That judgment, if based on substantial evidence of record, and if within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.

[Evidence Supports Finding as to  
Consumer Confusion]

None of the testimony which we have detailed can be said to be speculative or conjectural unless it be the conclusion of numerous witnesses, adopted by the Administrator, that the labeling and marketing of vitamin-enriched foods, not conforming to any standards of identity, tend to confuse and mislead consumers. The exercise of the administrative rule-making power necessarily looks to the future. The statute requires the Administrator to adopt standards of identity which in his judgment "will" promote honesty and fair dealing in the interest of consumers. Acting within his statutory authority he is required to establish standards which will guard against the probable future effects of present trends. Taking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values, there was sufficient evidence of "rational probative force" (see *Consolidated Edison Co. v. National Labor Relations Board*, 305 U. S. 197, 229, 230), to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue. *Federal Trade Commission v. Raladam Co.*, 283 U. S. 643, 651; *Federal Trade Commission v. Raladam Co.*, 316 U. S. 149, 151, 152; *Pacific States Box Co. v. White*, 296 U. S. 176, 181. Compare *McLean v. Fleming*, 96 U. S. 245, 251, 253-4, 255.

Respondent insists, as the court below held, that the consumer confusion found by the Administrator affords no basis for his conclusion that the standards of identity adopted by the Administrator will promote honesty and fair dealing. But this is tantamount to saying, despite the Administra-

Commission Act with only such changes as are necessary to adapt it to the pending bill", and he referred to "similar" provisions in the Bituminous Coal Commission Act, National Labor Relations Act, Securities Exchange Act, and Federal Communications Act. 83 Cong. Rec., 7892, 7777-8.



tor's findings to the contrary, either that in the circumstances of this case there could be no such consumer confusion or that the confusion could not be deemed to facilitate unfair dealing contrary to the interest of consumers. For reasons already indicated we think that the evidence of the desire of consumers to purchase vitamin-enriched foods, their general ignorance of the composition and value of the vitamin content of those foods, and their consequent inability to guard against the purchase of products of inferior or unsuitable vitamin content, sufficiently supports the Administrator's conclusions.

We have recognized that purchasers under such conditions are peculiarly susceptible to dishonest and unfair marketing practices. In *United States v. Carolene Products Co.*, 304 U. S. 144, 149, 150, we upheld the constitutionality of a statute prohibiting the sale of "filled milk"—a condensed milk product from which the vitamin content had been extracted—although honestly labeled and not in itself deleterious. Decision was rested on the ground that Congress could reasonably conclude that the use of the product as a milk substitute deprives consumers of vitamins requisite for health and "facilitates fraud on the public" by "making fraudulent distribution easy and protection of the consumer difficult."

[Purpose of Act To Authorize Food Standards]

Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from "economic adulteration," by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer ex-

pected to receive when purchasing a product with the name under which it was sold. Sen. Rep. No. 493, 73d Cong., 2d Sess., 10; Sen. Rep. No. 361, 74th Cong., 1st Sess., 10. The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained" (H. R. Rep. 2139, 75th Cong., 3d Sess., p. 2; H. R. Rep. 2755, 74th Cong., 2d Sess., p. 4), and to require informative labeling only where no such standard had been promulgated, where the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label. §§ 403 (g), 403 (i); see Sen. Rep. No. 361, 74th Cong., 1st Sess., 12; Sen. Rep. No. 493, 73rd Cong., 2d Sess., 11-12.

The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other.<sup>7</sup> We cannot say that such a standard of identity, designed to eliminate a source of confusion to purchasers—which otherwise would be likely to facilitate unfair dealing and make protection of the consumer difficult—will not "promote honesty and fair dealing" within the meaning of the statute.

[Unreasonableness of Standards Urged]

Respondent's final and most vigorous attack on the regulations is that they fail to establish reasonable definitions and standards of identity, as § 401 requires, in that they prohibit the marketing, under the name "farina," of a wholesome and honestly labeled product consisting of farina with vitamin D added, and that they prevent the addition of vitamin D to products marketed as "enriched farina" unless accompanied by the other prescribed vitamin ingredients which do not co-act with or have any diet-

<sup>7</sup> A Message of the President, dated March 22, 1935, urging passage of the bill and particularly of the standard of identity provision, pointed out that "The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearances with inward integrity. In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and produc-

ers are handicapped in any attempt to maintain higher standards." H. R. Rep. No. 2755, 74th Cong., 2d Sess., pp. 1-2.

The Chairman of the Food and Drug Administration testified before the Senate Committee that the provision for standards of identity which would reflect "the expectation of the buyer" was "one of the most important provisions of the Act." Hearings before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, pp. 35, 36.



ary relationship to vitamin D. Stated in another form, the argument is that it is unreasonable to prohibit the addition to farina of vitamin D as an optional ingredient while permitting its addition as an optional ingredient to enriched farina, to the detriment of respondent's business.

*[Standards of Reasonableness as Found in Act]*

The standards of reasonableness to which the Administrator's action must conform are to be found in the terms of the Act construed and applied in the light of its purpose. Its declared purpose is the administrative promulgation of standards of both identity and quality in the interest of consumers. Those standards are to be prescribed and applied, so far as is practicable, to food under its common or usual name, and the regulations adopted after a hearing must have the support of substantial evidence. We must reject at the outset the argument earnestly pressed upon us that the statute does not contemplate a regulation excluding a wholesome and beneficial ingredient from the definition and standard of identity of a food. The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition. As we have seen, the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give to consumers who purchase it under that name assurance that they will get what they may reasonably expect to receive. In many instances, like the present, that purpose could be achieved only if the definition of identity specified the number, names and

proportions of ingredients, however wholesome other combinations might be. The statute accomplished that purpose by authorizing the Administrator to adopt a definition of identity by prescribing some ingredients, including some which are optional, and excluding others, and by requiring the designation on the label of the optional ingredients permitted.<sup>8</sup>

Since the definition of identity of a vitamin-treated food, marketed under its common or usual name, involves the inclusion of some vitamin ingredients, and the exclusion of others, the Administrator necessarily has a large range of choice in determining what may be included and what excluded. It is not necessarily a valid objection to his choice that another could reasonably have been made. The judicial is not to be substituted for the legislative judgment. It is enough that the Administrator has acted within the statutory bounds of his authority, and that his choice among possible alternative standards adapted to the statutory end is one which a rational person could have made. *Houston v. St. Louis Independent Packing Co.*, *supra*, 487.

The evidence discloses that it is well known that the milling process for producing flours and farinas removes from the wheat a substantial part of its health-giving vitamin contents, which are concededly essential to the maintenance of health, and that many consumers desire to purchase wheat products which have been enriched by the restoration of some of the original vitamin content of the wheat. In fixing definitions and standards of identity in conformity with the statutory purpose the Administrator was thus confronted with two related problems. One was the choice of a standard which would appropriately identify unenriched wheat products which had

<sup>8</sup> The standard of identity provision was repeatedly stated in the Committee reports to have been patterned on the Butter Standards Act of 1923, 42 Stat. 1500. Sen. Rep. No. 361, 74th Cong., 1st Sess., 10; Sen. Rep. No. 646, 74th Cong., 1st Sess., 4; Sen. Rep. No. 493, 73d Cong., 2nd Sess., 10; H. R. Rep. No. 2139, 75th Cong., 3rd Sess., 5. That Act was entitled "An Act to define butter and provide a standard therefor", and establish a legislative definition and standard for butter. The Chairman of the House Committee which reported it said "The only things you can put into [butter] are salt, casein, the butter fat, and water. That is what the definition provides." Hearings, H. Committee on Agriculture on H. R. 12053, 67th Cong., 2nd Sess., p. 25; see also H. R. Rep. No. 1141, 67th Cong., 2nd Sess., p. 4.

Also referred to as models for the standards to be promulgated under the present act were the advisory standards then being promulgated by the Pure Food and Drug Administration under the authority given by the Appropriation Act of June 3, 1902, 32 Stat. 286, 296, and subsequent acts. Hearing before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, p. 36. (Statement of Walter B. Campbell, Chief of Food and Drug Administration, Dept. of Agriculture.) The announcements promulgating these standards stated that they were "so framed as to exclude substances not mentioned in the definition." E. g., Dept. of Agriculture, Food and Drug Administration, Service and Regulatory Announcement No. 2, Revision 4 (1933), p. 1; *id.*, Rev. 5 (1936) p. 1.



long been on the market. The other was the selection of a standard for enriched wheat products which would both assure to consumers of vitamin-enriched products some of the benefits to health which they sought, and protect them from exploitation through the marketing of vitamin-enriched foods of whose dietary value they were ignorant. In finding the solution the Administrator could take into account the facts that whole wheat is a natural and common source of the valuable dietary ingredients which he prescribed for enriched farina; that wheat is not a source of vitamin D; that milk, a common article of diet, is a satisfactory source of an assimilable form of calcium; that the principal function of vitamin D is to aid in the metabolism of calcium; and that milk enriched with vitamin D was already on the market.

We cannot say that the Administrator made an unreasonable choice of standards when he adopted one which defined the familiar farina of commerce without permitting addition of vitamin enrichment, and at the same time prescribed for "enriched farina" the restoration of those vitamins which had been removed from the whole wheat by milling, and allowed the optional addition of vitamin D, commonly found in milk but not present in wheat. Consumers who buy farina will have no reason to believe that it is enriched. Those who buy enriched farina are assured of receiving a wheat product containing those vitamins naturally present in wheat, and, if so stated

on the label, an additional vitamin D, not found in wheat.

[*Cost of Vitamin B<sub>1</sub>*]

Respondent speaks of the high cost of vitamin B<sub>1</sub> (\$700 per pound), but there was evidence that the cost of adding to flour the minute quantities of the four ingredients required for enriched farina would be about 75 cents per barrel, and respondent concedes that the cost to it may be but a fraction of a cent per pound. The record is otherwise silent as to the probable effect of the increased cost on the marketing of respondent's product. On this record it does not appear that the increased cost has any substantial bearing on the reasonableness of the regulation.

[*Standards Upheld*]

We conclude that the Administrator did not depart from statutory requirements in choosing these standards of identity for the purpose of promoting fair dealing in the interest of consumers, that the standards which he selected are adapted to that end, and that they are adequately supported by findings and evidence.

*Reversed.*

Mr. Justice MURPHY and Mr. Justice RUTLEDGE took no part in the consideration or decision of this case.

Mr. Justice ROBERTS is of opinion that the judgment should be affirmed for the reasons stated by the Circuit Court of Appeals, 129 F. 2d 76.

**COLUMBIA CHEESE CO., CONESTOGA CREAM & CHEESE  
MFG. CORP., EAST SMITHFIELD FARMS, INC., EDEL-  
STEIN DAIRY CO., INC., NEWARK CHEESE CO.,  
ROSEDALE DAIRY CO., INC., SODUS CREAM-  
ERY CORPORATION, AND MEYER ZAUS-  
NER v. PAUL McNUTT, AS FEDERAL  
SECURITY ADMINISTRATOR OF  
THE UNITED STATES**

United States Circuit Court of Appeals for the Second Circuit. No. 239,  
October Term, 1942. August 20, 1943. 137 F. 2d 576.  
Certiorari denied, 321 U. S. 777 (1944).

A petition was filed to review an order of the Federal Security Administrator promulgating regulations establishing definitions and standards of identity for cheeses. The scope of review of such an order does not allow the substitution of the court's judgment, although the court, on the same record, might reach a conclusion different from that of the Administrator.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.



The order must be affirmed if it is supported by substantial evidence of record and is within statutory and constitutional limitations.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

There was substantial evidence to support the choice by the Administrator of the name "Neufchatel" to describe cheese with a milk-fat content of from 20 to 32 per cent inclusive and a moisture content up to 65 per cent; and it was not the court's function to substitute its judgment of what might be a proper name for such a product for that of the Administrator.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Even though the name chosen by the Administrator for a product would drive a healthful product from the market, or depress existing standards of a product then being marketed, that name, or the name withheld from a product, could not be said by the court to be unreasonable or improper as long as there were findings and substantial evidence to support them which justified the action of the Administrator.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The findings of the Administrator covering the fat and moisture content of cream cheese and neufchatel cheese were supported by evidence, somewhat contradicted but substantial.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

The findings and regulations in respect to cottage and creamed cottage cheeses were required to be upheld on the evidence in the record; the requirement of pasteurization was supported by evidence and findings; and the regulation requiring the addition of 4 per cent of fat to the curd after the making of the curd, rather than before, was not unreasonable.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Martin A. Fromer (Martin A. Fromer and Leo Pfeffer, of counsel), for petitioners.

Wendell Berge, Assistant Attorney General; Oscar A. Provost and Edward G. Jennings, Special Assistants to the Attorney General (Edward B. Williams, Attorney, Federal Security Agency, of counsel), for respondent.

Before SWAN, CHASE, and CLARK, Circuit Judges.

[*Nature of Action*]

CHASE, Circuit Judge: The petitioners are cheese manufacturers who allege that they are adversely affected by the order and regulations which will be discussed later in greater detail and they brought this proceeding for judicial review in accordance with § 701 (f) of the Act, 21 U. S. C. A. § 371 (f), which provides for such a review in cases of actual controversy.

The administrative proceedings which led to the issuance of the order here under review began in August of 1939 with the object of establishing a definition and standard of identity for cream cheese; and these resulted in a proposed order which was issued on September 28, 1940, with findings of fact and a proposed regulation. But on application of the petitioners, who filed exceptions to the order, the hearing was reopened and consolidated with a hearing on proposals for standards for neufchatel, cottage

and creamed cottage cheeses. This hearing resulted in a final order of December 22, 1942, which substantially rejected petitioners' arguments in favor of standards which would allow lower fat and higher moisture content in the manufacture of these cheeses.

The regulations (Code of Federal Regulations, Title 21, Pt. 19) which are now under attack are in substance as follows: Sec. 19.515 requires that cream cheese contain by weight not less than 33% of milk-fat and not over 55% of moisture; that it must be made from a pasteurized starting mixture of cream with milk or skim milk or both, to which may be added lactic acid producing bacteria; that it may be "hot-packed" and that designated moisture-retaining gums, not to exceed 0.5% by weight, may be used provided the presence of these gums is stated on the label. Cream, milk or skim milk or a mixture of two or all of these may be used if the product is "hot-packed"; and



water, since it was not specified, may not be used. Sec. 19.520 sets the standard for neufchatel cheese and prescribes that the manufacture and basic ingredients be the same as cream cheese except that the milk fat content may vary from 20 to 32% inclusive and a moisture content up to 65% is allowed. Sec. 19.525 requires that cottage cheese have a moisture content of no more than 80% and that it be made from pasteurized sweet skim milk; and by Sec. 19.530 creamed cottage cheese must contain no more than 80% by weight of moisture and must be made so that at least 4% of milk fat is added by "mixing cottage cheese with pasteurized cream or a pasteurized mixture of cream with milk or skim milk or both."

#### *[Questions Presented]*

The questions presented on this review are whether the Administrator's definitions and standards of identity, establishing the fat and moisture content of cream and neufchatel cheeses are supported by substantial evidence of record; are reasonable definitions and standards of identity; will promote honesty and fair dealing in the interests of consumers; and establish definitions of the foods in question under their common names so far as is practicable; whether the standards which fail to provide for the addition of water in the "hot-pack" process of manufacture of cream and neufchatel cheeses are reasonable and based on substantial evidence; whether the cottage cheese standard, which requires the use of pasteurized skim milk, is valid under the Act and whether the standard requiring a maximum of 80% moisture content is based on substantial evidence; and finally, whether the creamed cottage cheese standard, which calls for the addition of milk fat after the making of the curd, and not before, is valid.

#### *[Finality of Administrator's Decision]*

It will be helpful to state at the outset that the scope of review of an order of the Administrator of the Federal Food, Drug, and Cosmetic Act is necessarily limited, as *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, shows clearly enough, and does not allow the substitution of the court's judgment, even though the court on the same record might reach a conclusion different from that of the Administrator. The order of the Administrator must, therefore, be affirmed if it is supported by substantial evidence of record and

is within statutory and constitutional limitations. The question, then, presented by this review is largely one of determining whether the Administrator's findings were supported by the evidence and whether his order conformed to the statutory purposes of the Act.

#### *[Identity of Cheeses]*

The Administrator found that there are produced and marketed various cheeses of a soft uncured nature, but that these cheeses, while they have similar characteristics, have separate and distinct identities. These cheeses have the same basic constituents (coagulated proteins of milk, soluble non-fat milk solids, and varying proportions of water and milk fat) and it is by changing the proportions of the basic constituents in the starting mixture that the differences in characteristics are obtained. Of these soft uncured cheeses cream cheese was found to be the relatively high-fat, low moisture cheese, containing traditionally from 35 to 40% or more of fat and 55 to 50% or less of moisture, although in good commercial practice the percentages might vary 2% above or below what the manufacturer sought to obtain.

#### *[“Hot-Pack” Process]*

One of the problems in the manufacture of cream cheese has been the leakage of moisture, which renders the cheese less attractive and correspondingly less merchantable. But in 1927 or thereabouts it was discovered that moisture leakage could be largely prevented by the addition of harmless vegetable gum, such as carob or locust bean gum, or karaya gum, or tragacanth gum; and it was found that the use of these gums for this purpose, up to 0.5% by weight, could not be abused when the moisture content of cream cheese is restricted. But following the discovery that gum could be used to prevent leakage it became the practice of many manufacturers to heat the gum and curd together so as to disperse the gum in the curd, by homogenization, and it became possible by this "hot-pack" process to raise the moisture and lower the fat content of the cheese without losing the appearance and texture of cream cheese. Thus it was found that most of the cheese made by this process contains from about 23 to 30% of fat and from about 60 to 65% of moisture, whereas cheese with the same percentage of fat and moisture made by the older method of manufacture would have



a softer texture than that which was found to be the traditional cream cheese. It was also found that the desired percentage of fat and moisture in the "hot-pack" process could be obtained by adding the proper amounts of cream or milk or skim milk, or any combination of these, before the curd is heated and homogenized; and that water has also been used for this purpose, although skim milk can be used to accomplish anything that water does in moisture adjustment.

*[Deception in Sale of Cheese]*

Consumers, it was found, cannot readily distinguish between the cream cheese made by the older process and the lower-fat, higher-moisture cheese made by the "hot-pack" process; and since fat content is the chief item of expense in such cheeses retailers sometimes sold the cheaper product as "cream cheese" which was natural enough since consumers, unlike manufacturers, wholesalers and retailers, were not always acquainted with or informed of the esoteric terms of qualification used in the trade, such as "low test," "cheap," "second grade," "No. 2," or as often as not by some arbitrary brand name. The cheaper product being sold consumers was found by the administrator to be more closely akin to neufchatel cheese, which was found to be the common or usual name of a cheese made by the same process as cream cheese, but having a fat content of a minimum of 20% and a moisture content of a maximum of 65%. This type of cheese, prior to about 1920, was marketed in substantial quantities, but gradually the market declined until it almost vanished because of a progressive cheapening of the product in quality.

*[Deleterious Effect of Bacteria]*

The findings in respect to the cottage cheese group were briefly, as follows: cottage cheese is made from skimmed milk in just about the same way as cream cheese is with a starting mixture that is usually something less than 1½% of milk fat and something less than 80% of moisture. A moisture content of no more than 80% was, therefore, found to be reasonable. By adding milk fat (4% was found to be reasonable) the product known as creamed cottage cheese can be obtained. This group of cheeses like cream cheese and neufchatel, was found to be highly perishable because of the growth of bacteria, yeasts and molds, which could to some extent be stop-

ped by pasteurization of the starting mixture, to which is then added lactic acid producing bacteria. These bacteria develop independently of the others and account for the eventual spoilage of the cheese. Some manufacturers have added chemicals to slow down the spoilage, but this was found to be uncommon as a trade practice, since consumers are generally acquainted with the process of spoilage and do not buy soft uncured cheeses in such quantities as to make this a real problem. Based on these findings the Administrator issued the regulations already referred to.

*[Objection to Name of Cheese]*

One of petitioners' chief objections to the regulations promulgated by the Administrator is that a substantial portion of the cheese manufactured by them must be designated as neufchatel cheese. This follows from the fact that much of their cheese contains 25 to 30% of milk fat and 57 to 61% of moisture. Petitioners take the position that the name neufchatel fails properly to identify their product and that it will mislead consumers; that it is foreign sounding, not easy to pronounce and has fallen into disrepute and dislike because of an inferior product formerly marketed under the name; that it imposes an unreasonable hardship on a whole industry; and that it will drive a wholesome product from the market. And they suggest that the Administrator would have done better if he had used the designation cream cheese with some sort of qualification such as Grade B or No. 2. But it is not our function, as has been pointed out before, to substitute our judgment of what might be a proper name for that of the Administrator. He chose the designation neufchatel; and there was substantial evidence to support such a choice. One witness, Stine, testified, for example, that consumers would be misled if the cheaper product continued to be labeled as cream cheese and he therefore recommended neufchatel as a good name. Moreover, there were findings supported by the evidence that neufchatel had been the name of that group of soft uncured cheeses which was next below the high fat content cheese commonly known as cream cheese. It was therefore within the power of the Administrator to identify cheeses of the kind that the petitioners make with the name he did. The fact that neufchatel had fallen into disrepute in the 1920's is of no particular significance so long as he



could find, as he did, that cheese made with a fat content of below 33% and with a moisture content of above 55% was not the product cream cheese as it was traditionally known. Nor does petitioners' assertion that these standards of identity will create a monopoly for one manufacturer make the order unlawful. If they continue to make the product they now make, they can sell it as neufchatel; and if they want to make a product that they can sell as cream cheese, they need only comply with the standards of the product that the Administrator has identified as cream cheese.

*[Actions of Administrator Justified]*

The petitioners also argue that the Administrator did not use the name, so far as it was practicable, which commonly identified the product sold; and that in the absence of a specific finding that it was not practicable to label their product cream cheese, the regulations identifying these various groups of cheeses must fall. The practicality of one name or another is not, of course, a matter for our judgment. Even though the name chosen would drive a healthful product from the market, or depress existing standards of a product now being marketed, that name or the name withheld from a product cannot be said by us to be unreasonable or improper so long as there were findings and substantial evidence to support them which justified the action of the Administrator. And there were such findings.

The many findings attacked by the petitioners as unsupported by substantial evidence are, as we have already intimated, supported by enough evidence so that they must stand even though this court on the same record might have reached a different conclusion. See *Security Adm'r. v. Quaker Oats Co.*, 318 U. S. 218, 228. Findings 20, 23 and 37, which cover the fat and moisture contents of cream cheese, are supported by evidence, somewhat contradicted to be sure, but nevertheless substantial, that much, if not most of the cream cheese sold before the discovery of the "hot-pack" process contained from 35 to 40% of fat and from 55 to 50% of moisture. And the Administrator also justifiably found that when the fat content went down and the moisture content up the appearance, smell, feel and taste of the resulting product became less characteristic of cream cheese as consumers knew it, although the demarcation was not easy to define. He, therefore, found it rea-

sonable to fix 33% of fat content or above as the proper figure for identifying cream cheese; and this figure was arrived at by allowing a 2% variation in the process of manufacture. And he set the maximum moisture content at 55%, which as the petitioners point out, was peculiar to say the least since a 2% variation was not allowed in this constituent of the product. But his decision on this score is supported by finding 22 which shows that a product of more than 55% of moisture, if not subjected to the "hot-pack" process, acquires different but closely related characteristics of cream cheese. That determination was not unreasonable in view of the evidence of leakage if the moisture content exceeded this amount in the absence of the use of moisture retaining gums. The finding that water was sometimes used by manufacturers in adjusting the moisture content, but that skim milk could accomplish the same result, and was therefore prescribed, was also supported by evidence that in good commercial practice water was not used. The Administrator could believe this if he chose because, as we reiterate, it is his judgment and not ours that must be given effect when based upon facts in evidence. As to the finding that the cheaper product was not accompanied by a uniform differentiation in price, the evidence was again conflicting but yet substantial. That is likewise the case with findings 11 and 41 which relate to the fat content of the starting mixtures.

*[Findings Upheld]*

The findings and regulations in respect to cottage and creamed cottage cheeses must also be upheld on the evidence in this record. The prescription of a moisture content of no more than 80% was based on substantial evidence that most cottage cheese in good practice contained no more than this and usually contained less. As to the requirement of pasteurization, this was supported by evidence and findings that it was usually done and that it prevented spoilage to some degree in a highly perishable product by killing bacteria, yeasts and molds not necessary to the manufacture of the cheese. And the regulation requiring the addition of 4% of fat to the curd after the making of the curd, instead of before, was not unreasonable. Even though some manufacturers might prefer to use a process differing from the one required, it was permissible on the evidence for the Admin-



*U. S. Cane Sugar Refineries' Ass'n v. McNutt*

istrator to conclude that good commercial practice and a proper identification of the product called for in the addition of fat after the formation of the curd since there was evidence that the resulting product was different.

Bound as we are by these adequately supported findings of the Administrator, *Security Adm'r v. Quaker Oats Co.*, *supra*, his action based upon them cannot be disturbed.

Affirmed.

### Dissenting Opinion

SWAN, Circuit Judge: I am unable to agree with my brothers that the order should be in all respects affirmed.

For many years cheese having less than 33% of milk fat has been sold as "cream cheese." Almost every one in the industry, with the exception of the Kraft Cheese Co., objects to the requirement that such cheese hereafter be called "neufchatel." The statute, 21 U. S. C. A. § 341, authorizes the Administrator to promulgate regulations "establishing for any food under its common or usual name so far as practicable, a reasonable definition and standard of identity," etc. There is no finding that it is impracticable to use the common name and distinguish between cheese of different milk fat content by adjectives, for example, light cream cheese or heavy cream cheese. With-

out at least a finding of impracticability, I think it unreasonable to deprive the bulk of the industry of their good will in the commonly used name.

Next, take the standard of 33% fat and 55% moisture. Finding 21 says that in good commercial practice the percentages of fat and moisture vary as much as 2% above or below. In recognition of such variation the 35% for fat (Finding 20) was dropped to 33, but the 55% for moisture was not raised to 57%. This seems to me an arbitrary disregard of Finding 21.

As to the prohibition against adding water in the "hot-pack" process, there is a finding that water is sometimes used (Finding 27) and no finding of any reason why that practice must be discontinued. I think the findings fail to support this part of the order.

As to the cottage cheese the Administrator ignored the evidence as to the use of unpasteurized skimmed milk. He made no finding on the subject. The right to present evidence is a barren one if the trier of fact may fail to consider it. See *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 120 F. 2d 258, 261 (C. C. A. 7). I would send the case back for findings before approving this part of the order.

I agree that the order is supportable in so far as it relates to creamed cottage cheese.

UNITED STATES CANE SUGAR REFINERS' ASSOCIATION,  
UNITED STATES BEET SUGAR ASSOCIATION, THE  
AMERICAN SUGAR REFINING COMPANY, CALI-  
FORNIA AND HAWAIIAN SUGAR REFINING  
CORPORATION, LIMITED, THE NATIONAL  
SUGAR REFINING COMPANY, AND SA-  
VANNAH SUGAR REFINING COR-  
PORATION v. PAUL V. McNUTT,  
AS FEDERAL SECURITY AD-  
MINISTRATOR OF THE  
UNITED STATES

United States Circuit Court of Appeals for the Second Circuit. No. 307.  
October Term, 1942. August 27, 1943. 138 F. 2d 116.

A petition was filed to review an order of the Federal Security Administrator promulgating regulations establishing definitions and standards of identity for canned apricots, cherries, peaches, and pears. The regulations provided that dextrose and corn sirup might be used in stated proportions in combination with sugar as optional sweetening ingredients, without the specific name of the ingredient being disclosed on the label. Petitioners, marketers of sucrose, would have no standing to appeal, Section 701 (f) (1) aside, by virtue solely of added competition made possible by regulations



Federal Food, Drug, and Cosmetic Act  
*U. S. Cane Sugar Refineries' Ass'n v. McNutt*

promulgated under Section 401, since that would be *damnum absque injuria*.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

To support a petition to review an order issued under Section 401, the petitioner must be "adversely affected" by the order and there must be a "case of actual controversy."

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

In order that a petitioner may be considered to be "adversely affected," the adverse effect of the regulations must be something more than nominal or highly speculative, and of sufficient immediacy and reality.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Petitioners, marketers of sucrose, were not sufficiently adversely affected by regulations permitting the use in the standardized food of a product in competition with petitioners' without disclosing its specific name on the label, so as to have standing to seek review of the order. Therefore, the court had no jurisdiction to review the regulations.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

It is inconceivable that Congress intended to permit all persons who could show a remote and uncertain likelihood that regulations promulgated under Section 401 would injuriously affect the market for their produce to file petitions to review merely because they had decided that they had been, or might be, put in danger of that.

Sections 401, 701 (f), Federal Food, Drug, and Cosmetic Act.

Sullivan & Cromwell (L. A. Crosby and Philip L. Miller of counsel), for petitioners.

Wendell Berge, Assistant Attorney General; Oscar A. Provost and Edward G. Jennings, Special Assistants to the Attorney General (Edward B. Williams, Attorney, Federal Security Agency, of counsel), for respondent.

Before SWAN, CHASE and CLARK, Circuit Judges.

Petition by United States Cane Sugar Refiners' Association and others to review an order of Paul V. McNutt, Federal Security Administrator promulgating amended regulations fixing definitions and standards of identity, under the provisions of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040; 21 U. S. C. A. §§ 301-392), for canned apricots, cherries, peaches and pears. The respondent answered and also moved to dismiss the petition. Petition dismissed.

[Statutory Provisions]

CHASE, Circuit Judge: After extensive hearings held in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1040; 21 U. S. C. A. §§ 301-392), the Federal Security Administrator promulgated amended regulations which established definitions and standards of identity for canned apricots,

cherries, peaches and pears. In so doing he undertook to act pursuant to § 401 of the above statute which provides as follows:

"Sec. 401. Whenever in the judgment of the Administrator<sup>1</sup> such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container; \* \* \*. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. \* \* \*".

<sup>1</sup> By Reorganization Plan No. IV (54 Stat. 1234), the Federal Food and Drug Administration was transferred from the Department of Agriculture to the Federal Security Agency and the functions of the Secretary of Agriculture in

the administration of the Act were transferred to the Federal Security Administrator. The terms actually used in this statute have been changed accordingly.



*U. S. Cane Sugar Refineries' Ass'n v. McNutt*

Sec. 403 provides (a) that a food shall be deemed misbranded if in any particular its label is false or misleading; or inter alia, if it purports to be, or is represented to be, a food for which a definition and standard of identity has been promulgated as provided in § 401 unless (g) (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients \* \* \* present in such foods.

By virtue of § 701 (e) the Administrator may act upon his own motion or upon the application setting forth reasonable grounds for action, of all, or a substantial portion of any interested industry. When he does take such action he is required to hold a public hearing upon any proposal to issue, amend, or repeal any regulation contemplated by certain sections of the statute of which § 401 is one and at the hearing any interested person may be heard in person or by his representative. The Administrator shall make public his action in issuing, amending and repealing the regulation, or in determining not to take such action, as soon as practicable after completion of the hearing.

Sec. 701 (f) (1) provides that:

"In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may \* \* \* file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. \* \* \*".

Sec. 701 (f) (3) confers jurisdiction upon such Circuit Court of Appeals, (so far as now invoked) to affirm the order, or to set it aside in whole or in part temporarily or permanently. It provides that the findings of the Administrator as to the facts shall be conclusive if they are supported by substantial evidence.

*[Standard for Canned Apricots, Cherries, Peaches and Pears]*

Following the above mentioned hearings, at which all these petitioners were represented, the Administrator duly promulgated, with regulations, the order which the petitioners are now seeking to have reviewed. Insofar as we are presently concerned the regulations dealt with the sweetening ingredients of the canned fruits previously mentioned and in respect to canned peaches, which may be taken as typical for all, pro-

vided in substance that all sugar might be used for sweetening though, as optional saccharine ingredients, dextrose might be used in stated proportions in combination with sugar and so might corn sirup. For the purposes of the regulations sugar was defined as "refined sucrose or invert sugar sirup. The term 'invert sugar sirup' means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent of weight of ash, and which is colorless, odorless, and flavorless except for sweetness." Dextrose was defined as "the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch." Corn sirup was defined as "an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

It was further provided that the optional packing media which contained an added sweetener, that might be sucrose or sucrose in combination with dextrose or with dextrose and corn sirup, should be designated as (3) slightly sweetened water or (4) light sirup; or (5) heavy sirup; or (6) extra heavy sirup; or (7) slightly sweetened peach juice; or (8) light peach juice sirup; or (9) heavy peach juice sirup; or (10) extra heavy peach juice sirup; as the case might be. And when a sweetened packing media was used it was made a sufficient compliance with labeling requirements in that respect to use only the appropriate name from the above list without disclosing the fact that the sweetener was all sugar or sugar in one of the permitted combinations. Before this, canners of these fruits might use dextrose or corn sirup as a sweetener only if that fact was disclosed on the label. It is because this requirement was done away with that the petitioners now contend that they were adversely affected in a case of actual controversy to give them "standing to appeal" so as to bring this petition to review within the scope of § 701 (f) (1).

The regulations further provided in respect to the content of the optional packing media already listed by name and the proportions to sucrose in which dextrose and corn sirup might be used that:

"As used in this paragraph the term 'water' means, in addition to water, any mixture of water and peach juice; and the term 'peach juice' means the fresh or canned expressed juice of mature peaches, of any varietal group, specified in para-



graph (b) of this section, to which no water is added, directly or indirectly.

"Each packing media (3) to (10), inclusive, is prepared with a liquid ingredient and a saccharine ingredient.

" \* \* \* The saccharine ingredient from which packing media (3) to (10), inclusive, are prepared is one of the following: sugar; or any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; or any combination of sugar and corn sirup in which the weight of the solids of the corn sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup in which twice the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup used is not more than the weight of the solids of the sugar used; except that packing media (7) to (10), inclusive, are not prepared with any invert sugar sirup or corn sirup other than dried corn sirup, \* \* \*."

There was appended a prescribed range of densities, as measured on the Brix hydrometer fifteen days after the peaches were canned, for packing media (3) to (10) inclusive.

One result was to permit canners of the fruits to use some dextrose or corn sirup or both in combination with sugar without in express terms so labeling the product. As both of these optional sweeteners, though less sweet than sugar, were less expensive to use, the petitioners were convinced that fruit canners would be induced to use them to avoid the use of sugar, and, to the extent that this might be done, consider themselves adversely affected by the order.

[*Sugar Refiners Not Adversely Affected by Fruit Standards*]

The respondent, though defending his order on the merits as well, first contends that the petition to review must be dismissed on the ground that the petitioners brought it not as consumers of the regulated product or even as competitors in the production and sale of it, but only in their supposed right as suppliers of an ingredient used in the manufacture of it. We will, accordingly, first attempt the solution of that rather difficult problem.

It is clear that the petitioners are "adversely affected" only by way of some competition with dextrose or corn sirup producers and suppliers or both which but for the statute and the result of its admin-

istration they would encounter anyway and to a greater degree. And it is adequately clear that they would have no standing to appeal, § 701 (f) (1) aside, by virtue solely of added competition made possible or probable by regulations promulgated in accordance with § 401. That would be but *damnum absque injuria* as Judge Frank has recently shown in his comprehensive opinion where an analogous situation was considered under the Bituminous Coal Act of 1937. (15 U. S. C. A. §828 *et seq.*) *Associated Industries of New York State, Inc. v. Ickes*, 134 F. (2) 694. Nevertheless a motion to dismiss was there denied and the right to review in behalf of consumers of the regulated product was upheld on the ground that a consumer faced with the prospect of having to pay higher prices for coal because of the order was a "person aggrieved" within the provisions of § 6 (b) of the Act. The reasoning which led to that conclusion would, we think, apply as well to a petition to review in accordance with § 701 (f) (1) of the statute here involved brought by one who would be "adversely affected" if the order became effective provided, of course, there was "a case of actual controversy as to the validity" of the order which must be more than merely colorable. *Land O'Lakes Creameries, Inc. v. McNutt*, 132 F. (2) 653; *A. E. Staley Company v. Secretary of Agriculture*, 120 F. (2) 258. The latter requirement, obviously, can have substance only when it is based upon some action of the Administrator by which petitioners are "adversely affected" within the statutory meaning of that term. If they are not so affected they can present no actual controversy of which the court can take cognizance. On the other hand persons might be "adversely affected" by action of the Administrator so clearly lawful that there would be no "case of actual controversy" to make a petition to review more than merely frivolous. And so to support a petition to review both these requirements must be met. We do not find it presently necessary to deal with them separately, however.

In both of the cases just cited the right to review regulations promulgated under the statute here involved was upheld. That was accompanied with the expression of some doubt on the part of the court in the *Land O'Lakes* case where the regulations had fixed a definition and standard of identity for oleomargarine and the petitioners were manufacturers and purveyors of butter, a product already in competition with oleo-



*U. S. Cane Sugar Refineries' Ass'n v. McNutt*

margarine and put into keener competition with it as a result of the regulations. That case differs from the instant one in no material respect unless it is distinguishable on the ground that here the competition the petitioners are called upon to meet is too problematical to affect them adversely within the meaning of § 701 (f) (1).

In the *Staley* case the "actual controversy" of which the court took cognizance on a petition to review regulations promulgated under the instant statute, was between a purveyor of corn sirup which, but for the regulations, could be used as an ingredient in making sweetened condensed milk and purveyors of sugar whose use was freely permitted. The regulations excluded such use of corn sirup entirely and so deprived the petitioner of all opportunity to compete in that field in the future. It was held that that "adversely affected" it and was enough to support the questioned jurisdiction of the petitioner under § 701. The instant case is closely akin to the *Staley* case and yet it does not fall readily into what we conceive to be the meaning of the term "adversely affected" in the light of the principles relied on in our *Associated Industries* case. The supposed adverse effect is one which leaves the petitioners' product free of all restriction. The petitioners are "adversely affected" only in that their competitors are not hampered more. But though such a relationship to the subject matter of the regulations may be enough in some instance which does not now come to mind, it can only be so when the adverse effect of the regulations, present or future, is "of sufficient immediacy and reality." *Maryland Casualty Co. v. Pacific Oil & Coal Co.*, 312 U. S. 270. The adverse effect must be a result that is not only reasonably sure to follow the enforcement of the regulations but will be "something more than nominal or highly speculative." *National Broadcasting Co. v. Federal Communications Commission*, 132 F. (2) 545, 548. It is inevitable that such regulations as these will affect in one way or another a large number of persons. In a sense they "affect" the public at large for whose benefit they are promulgated. It is to be expected that this effect may be thought to be "adverse" by a lesser, but still large number of persons not engaged in making or selling the standardized product. It is, however, inconceivable that Congress intended to permit all persons who could show a remote and uncertain likelihood that the regulations would

injuriously affect the market for their produce to file petitions to review merely because they decided that they had been, or might possibly be, put in danger of that. In order to prevent such obstruction to the orderly administration of the statute by virtually unlimited petitions to review, it is necessary that the class of petitioners who have "standing to sue" be confined to those who can show some direct adverse effect traceable with reasonable certainty to the regulations promulgated.

As we said in the *Associated Industries* case, a consumer threatened with the prospect of having to pay higher prices for coal because of an order which fixes prices and prevents competition among those from whom the consumer purchases is a person "aggrieved." The effect in that instance was direct as well as certainly adverse. So, too, increased competition may be enough, though the policy behind the statute is to maintain competitive practices that are in the public interest, to show that a person has been "adversely affected" by an administrative order. *Commission v. Sanders Radio Station*, 309 U. S. 470. Yet giving effect to such considerations by no means requires their extension to include all persons whose desire to review such regulations as these happens to be created by the mere possibility of having to meet competition in business they would rather have eliminated. The paramount need for the orderly and the reasonably expeditious administration of the statute by the official charged with the duty of making it effective in the public interest creates at least the need of limitations upon the construction of the term "adversely affected" to do away with delays that otherwise could be brought about by persons upon whom the adverse effect of the regulations would at most be so negligible that it should be disregarded to effectuate the public interest the statute was designed to promote.

When the regulations are considered in the light of their effect upon the petitioners, it seems adequately clear that the latter do not fall into the class Congress has authorized to seek a review. The regulations do not prevent the use of sugar in the canning of these fruits to whatever extent canners may desire to use it. On the contrary, they require its use in every instance and so far as that requirement makes necessary the use of more sugar than before there is, of course, no adverse effect upon petitioners. What then is the threatened increased com-



petition which the petitioners face? It is merely that the canners may use the permitted amounts of either dextrose or corn sirup or both without mentioning those products by name on the label of their product. There is no claim that the permitted sweeteners, other than sugar, are not wholesome or that consumers would be dissatisfied with the products so sweetened and erroneously attribute their dislike to the use of sugar as a sweetener. What the petitioners are really claiming is that the regulations will do away with the remote, speculative sales resistance of the public to the marketing of the canned fruits sweetened in some part with dextrose or corn sirup which might be present if the labels on the

cans disclosed, by naming them, that the permitted amounts of one or the other or both of the optional sweeteners had been added to the required sugar. If such a tenuous likelihood of injury were enough to cause the petitioners to be "adversely affected," the opportunity for maintaining petitions to review such regulations as these would be so unlimited as to be a serious threat to the practical administration of the statute. In our opinion, therefore, petitioners neither have been, nor will be, adversely affected within the meaning of § 701 (f) and this court, accordingly, has no jurisdiction to review the regulations.

[Petition for Review Dismissed]

Petition dismissed for lack of jurisdiction.

## MARTIN COUGHLIN, TRADING AS DIAMONEX CO. v. FEDERAL SECURITY ADMINISTRATOR

United States District Court for the Northern District of Illinois. November 9, 1944. Notices of Judgment Summarizing Judicial Review of Orders Under Sections 701 (f) and 505 (h) of the Federal Food, Drug, and Cosmetic Act (No. 7) Issued July 1946.

Petitioner filed a petition to review and set aside an order of the Federal Security Administrator which ordered that petitioner's application with respect to a new drug should not become effective. In entering a judgment affirming the order, findings of fact and conclusions of law were handed down. The district court concluded that the petitioner's application had not become effective; that the petitioner had failed to avail himself of the opportunity for a hearing afforded him by respondent, had failed to exhaust his administrative remedies, and had failed to urge before the respondent the objection that respondent's findings and order were not supported by substantial evidence; that the respondent's findings and order that the petitioner's application should not become effective were supported by substantial evidence and were conclusive; and that the order should be affirmed.

Sections 505 (a), 505 (b), 505 (c), 505 (d), 505 (h), Federal Food, Drug, and Cosmetic Act.

### Findings of Fact and Conclusions of Law

BARNES, District Judge: This cause having come on to be heard on petitioner's appeal from the order of the respondent refusing to permit petitioner's application with respect to its new drug "Diamonex" to become effective, the Court hereby files its findings of fact and conclusions of law as follows:

#### The Court Finds:

1. The petitioner is, and was during the times mentioned in the petition, a resident of Cook County, Illinois, and during the times mentioned in the petition was engaged in the purchase and sale of drugs in interstate commerce under the name of The

Diamonex Company.

2. On February 12, 1943, petitioner filed with respondent an application with respect to petitioner's new drug "Diamonex" under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 355).

3. On March 3, 1943, a letter was sent to petitioner by the Commissioner of Food and Drugs informing petitioner that his application had been filed with respondent on February 12, 1943, and that the application as filed did not demonstrate adequately the safety of the drug if sold as was proposed by petitioner, for indiscriminate use by the lay public. Said letter of March 3, 1943, further advised petitioner that he might



deem it advisable to limit the distribution of the drug for use by or on the prescription of a physician, and that to accomplish that purpose the directions appearing on the label of the drug should be deleted and the statement "Caution: To be used only by or on the prescription of a physician" inserted in lieu thereof.

4. On April 3, 1943, respondent, pursuant to the authority contained in Section 505 (c) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 355 (c)), and prior to the sixtieth day after the filing of petitioner's application, postponed the effective date of petitioner's application for one hundred and eighty days after the filing thereof to enable proper study and investigation of petitioner's application.

5. Pursuant to Section 505 (d) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 355 (d)), the respondent, on June 8, 1943, sent notice in writing to the petitioner and the Diamonex Company of an opportunity for a hearing to be held at 10:00 A.M., on July 9, 1943, in the City of Washington, District of Columbia. Said notice of hearing stated that the preliminary examination of petitioner's application indicated that conditions prevailed which justified respondent in issuing an order refusing to permit petitioner's application to become effective, designated an Examiner to conduct the hearing, and stated the issues to be determined at said hearing. Said notice of hearing required the petitioner to enter a written appearance with the Hearing Clerk of the Federal Security Agency and stated that if petitioner elected not to avail himself of an opportunity for a hearing, the respondent, without further notice, might find that upon the basis of the information submitted to him as a part of the application he had insufficient information to determine whether the drug "Diamonex" was safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling of said product; and that respondent might issue an order refusing to permit the said application to become effective. Said notice of hearing further stated that failure to file a written appearance as aforesaid would be construed as an election by petitioner not to avail himself of the opportunity for the hearing, and in the event of such failure the respondent, without further notice, might enter an order, upon the basis of the information submitted to him as a part of the application, refusing to permit the application to

become effective. Said notice of hearing further stated that if petitioner elected to avail himself of the opportunity for hearing, he might present at such hearing such evidence as was within the issues set forth in said notice of hearing; that after the completion of the hearing petitioner might file with the Hearing Clerk suggested findings of fact, conclusions, and order, based solely on the evidence of record at the hearing; that the Examiner would thereafter prepare a report containing proposed findings of fact, conclusions, and order, which would be served upon the parties to said hearing; and that petitioner might thereafter file with the Hearing Clerk a written statement concerning each of the objections to the Examiner's report upon which he wished to rely, referring where relevant to the proper pages of the transcript of the evidence and suggesting the corrections which he desired to be made, but that no objection would be considered which might reasonably have been, but was not, made at the hearing. Said notice of hearing further stated that as soon as practicable thereafter, and upon the basis of the whole record and his consideration thereof, the respondent would issue his final order and that a copy would be served upon petitioner.

6. On June 29, 1943, petitioner filed with respondent a special appearance and motion to vacate the said notice of hearing of June 8, 1943, on the ground that the application of petitioner had become effective on April 13, 1943. Said motion was denied by respondent on July 6, 1943.

7. On July 9, 1943, petitioner filed with respondent a request for rehearing on said motion to vacate, which request was denied by respondent on July 13, 1943.

8. The petitioner failed to enter a written appearance with the said Hearing Clerk of the Federal Security Agency as provided in said notice of hearing dated June 8, 1943, and failed to avail himself of any and all of the opportunities offered and made available to him in said notice of hearing.

9. On August 6, 1943, the respondent found, upon the basis of the information submitted to him as part of petitioner's application, and upon the basis of other information before respondent with respect to said drug "Diamonex", that there was insufficient information upon which to determine whether the said drug "Diamonex" was safe for use under the conditions pres-



cribed, recommended, or suggested in the proposal labeling of said drug, and ordered that the aforesaid application of petitioner (trading as The Diamonex Company) with respect to the new drug called "Diamonex" should not become effective.

10. Thereafter, petitioner filed a petition in this Court that said order of respondent of August 6, 1943, should be reviewed and set aside; and on October 1, 1943, this Court ordered that petitioner be allowed to file said petition with the Clerk of this Court and that said action should be docketed and placed on the calendar in accordance with the rules and practice of this Court for the purpose of a review of said order of respondent as provided by law. Thereafter, respondent prepared, certified, and filed with the Clerk of this Court, and within sixty days from the date of said order of October 1, 1943, of this Court, a complete transcript of said entire proceeding had by and before respondent concerning petitioner's application with respect to petitioner's new drug "Diamonex," and thereafter respondent filed with the Clerk of this Court an answer to said petition.

**The Court Files the Following  
Conclusions of Law:**

1. The said application of petitioner (trading as The Diamonex Company) with respect to his new drug "Diamonex" did not become effective on the sixtieth day after it was filed on February 12, 1943, or on any day theretofore or thereafter.

2. The petitioner (trading as The Diamonex Company) failed to avail himself of the opportunity for a hearing afforded him by respondent, failed to exhaust his administrative remedies, and failed to urge before the respondent the objection that respondent's findings and order of August 6, 1943, were not supported by substantial evidence.

3. The respondent was authorized, and had jurisdiction, to make said findings and order of August 6, 1943.

4. The finding of August 6, 1943, of the respondent, that, upon the basis of the information submitted to respondent as part of petitioner's application, and upon the basis of other information before respondent with respect to said drug "Diamonex," there was insufficient information upon which to determine whether the said drug "Diamonex" was safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling of said drug, and the said order of the respondent dated August 6, 1943, that the aforesaid application of petitioner (trading as The Diamonex Company) with respect to the new drug called "Diamonex" should not become effective, were supported by substantial evidence and are conclusive.

5. Said order of the respondent dated August 6, 1943, should be affirmed.

Let the foregoing Findings of Fact and Conclusions of Law be filed and judgment be entered accordingly.

**AMERICAN LECITHIN COMPANY, INC., v. PAUL V.  
McNUTT, AS FEDERAL SECURITY ADMIN-  
ISTRATOR OF THE UNITED STATES**

United States Circuit Court of Appeals for the Second Circuit.

No. 212. May 27, 1946. 155 F. 2d 784.

Certiorari denied, 329 U. S. 763 (1946).

A petition was filed to review an order of the Federal Security Administrator promulgating regulations establishing definitions and standards of identity for cacao products. Petitioner, manufacturer of lecithin, asserted that the Act conferred no power on the Administrator to require petitioner's product to be designated on the labels of cacao products by any word other than "lecithin," and that the provision of the regulation requiring, when lecithin was added as an optional ingredient, that the label bear the term "emulsifier," was erroneous. The Government conceded that the term "lecithin" could be used provided the prescribed label declaration was observed. The order, so construed, did not "adversely affect" the petitioner, since its customers were privileged to use or not use the word "lecithin" on their labels and inasmuch as petitioner could not be damaged by the addition of the word "emulsifier" as descriptive of lecithin.

Sections 401, 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.



Baer & Marks, for petitioner.

Theron L. Caudle, Assistant Attorney General, James B. Goding, Attorney, Federal Security Agency, and Vincent A. Kleinfeld, Attorney, Department of Justice, for respondent.

Before SWAN, CLARK and WOODBURY, Circuit Judges.

[*Nature of Proceedings*]

SWAN, Circuit Judge: The petitioner is engaged in the business of manufacturing and selling lecithin, which is a product extracted from soy beans and used by manufacturers of cacao products, such as sweet and milk chocolate and chocolate coated candies. The order of which the petitioner seeks judicial review fixes definitions and standards of identity for cacao products and permits the use of lecithin as an optional ingredient in such products, but, when so used, requires the label to carry the statement "Emulsifier Added" or "With Added Emulsifier."

The petitioner does not challenge the respondent's determination of standards of identity but asserts that the statute confers no power to order petitioner's product to be designated on labels by any word other than "lecithin," and that the term "emulsifier" is erroneous as applied to lecithin in chocolate products. It prays that the order be set aside only in so far as it (1) requires the above mentioned label statement for the optional ingredient lecithin and (2) "prohibits the use of the specific word 'lecithin' as the label statement for petitioner's product when used as an optional ingredient" in cacao products.

[*Petitioner Not "Adversely Affected"*]

The first problem for consideration is whether we have jurisdiction to review the order. The respondent's authority to make the order is to be found in section 401 of the Act, 21 U. S. C. A. § 341. The provisions for review of such an order appear in section 701 (f), 21 U. S. C. A. § 371 (f). This section provides that "In a case of actual controversy as to the validity" of any such order, "any person who will be adversely affected by such order if placed in effect" may petition the appropriate circuit court of appeals for a judicial review of the order. The respondent contends that the petitioner is not a person "adversely affected" by the order "in a case of actual controversy." The petitioner is not a member of, nor does it represent the cacao products industry. The order does not touch the manner in which the petitioner's business shall be conducted: petitioner may still

sell its product under the name "lecithin." The label requirements are directed only to its customers. Nor does the order, as the petitioner's prayer for relief has erroneously assumed, "prohibit" them from using the word "lecithin" on their labels provided they observe the prescribed label declaration: that is to say, petitioner's customers may if they wish, use a label statement reading "Emulsifier Lecithin Added" or "With Added Emulsifier Lecithin." That such a label would comply with the order is expressly conceded in the respondent's brief. We accept this reasonable construction by the Administrator of his own order and shall decide the question of jurisdiction on this basis. So construed the order does not, in our opinion, "adversely affect" the petitioner. Since its customers are privileged at their option to use or not use the word "lecithin" on their labels, if they do not use it it is their election, not the terms of the order, which will deprive the petitioner of any advertising or competitive advantage that might be gained from having the label carry the word "lecithin." Nor can we see how the petitioner can be damaged by the addition of the word "emulsifier" as descriptive of lecithin. The findings of fact made by the respondent state that emulsifiers are commonly added to sweet chocolate and that lecithin and other named substances "are suitable for use as such emulsifying ingredients."

[*Cases Differentiated*]

In support of its right to a judicial review the petitioner relies on *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 120 F. 2d 258 (C. C. A. 7) and *Land O'Lakes Creameries, Inc. v. McNutt*, 132 F. 2d 653 (C. C. A. 8). In the *Staley* case the effect of the order was to prevent makers of sweetened condensed milk from using petitioner's corn syrup as a sweetener. In the *Creameries* case the effect of the order was to put oleomargarine into keener competition with petitioner's butter. Both of those cases were differentiated by this court in *U. S. Cane Sugar Refiners' Assn. v. McNutt*, 138 F. 2d 116, where cane sugar producers objected to an order which permitted fruit canners to use dextrose and corn syrup as



optional ingredients without having so to state on the labels. We held that any adverse effect of that order was too remote and indirect to give the petitioner standing to review the order. In the case at bar the damage is even more speculative than in the

*Cane Sugar* case, for it will turn on whether or not the petitioner's customers elect to mention lecithin as the emulsifier they have added.

Petition dismissed for lack of jurisdiction.

WASHINGTON STATE APPLE ADVERTISING COMMISSION ET AL. v. FEDERAL SECURITY ADMINISTRATOR  
 WASHINGTON STATE GRANGE ET AL. v. FEDERAL SECURITY ADMINISTRATOR

United States Circuit Court of Appeals for the Ninth Circuit. Nos. 10,947 and 10,952. July 24, 1946. 156 F. 2d 589.

Petitions were filed for the review of an order issued by the Federal Security Administrator limiting the quantity of fluorine remaining as insecticidal residue on apples and pears. The order would affect only those who had some interest in apples and pears on which fluorine would remain as insecticidal residue, and it did not appear that any petitioner had any such interest.

Sections 406 (a), 701 (e), 701 (f), Federal Food, Drug, and Cosmetic Act.

The statements in the petitions that "fluorine spray, namely cryolite," and "fluorine in the form of cryolite" were used might be disregarded, since the court knew judicially that fluorine and cryolite are not the same thing, fluorine being a gas and cryolite a solid.

Sections 406 (a), 701 (f), Federal Food, Drug, and Cosmetic Act.

It was immaterial whether cryolite remained as an insecticidal residue, since the order did not limit the quantity of cryolite remaining; and inasmuch as the petitions did not reveal that fluorine remained on the fruit, the petitioners were not adversely affected and the petitions would be dismissed.

Sections 406 (a), 701 (f), Federal Food, Drug, and Cosmetic Act.

Smith Troy, Attorney General of Wash., Harold Pebbles, Chief Assistant Attorney General of Wash., and Elwood Hutcheson, Special Assistant Attorney General of Yakima, Wash., for petitioners in cause No. 10947.

Norman A. Eisner, San Francisco, Cal., for petitioners in cause No. 10952.

Theron L. Caudle, Assistant Attorney General, Washington, D. C., and Frank J. Hennessy, U. S. Attorney, San Francisco, Cal. (Vincent A. Kleinfeld and John T. Grigsby, Attorneys, Department of Justice, Washington, D. C., of counsel), for respondents.

Before MATHEWS, STEPHENS and HEALY, Circuit Judges.

[*Nature of Proceeding*]

MATHEWS, Circuit Judge: Petitioners seek review of an order issued by respondent under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. §§ 301-392. Thereby respondent promulgated the following regulation (9 F. R. 11836, 21 C. F. R., 1944 Supp., § 120.1):

"The quantity of fluorine remaining as insecticidal residue on apples and pears is hereby limited to not more than 7 milligrams of fluorine, calculated as F, per kilogram of each such fruit."

Unless they will be adversely affected by the order, if placed in effect, petitioners are not entitled to a review thereof. See § 701 (f)(1) of the Act, 21 U. S. C. A. § 371 (f)(1). Each petition states that the petitioners named therein will be so affected. This, however, is a mere statement of a conclusion. Neither petition states facts warranting the conclusion.

[*Petitioners Not Owners of Apples and Pears with Fluorine Spray Residue*]

The order, if placed in effect, will affect



only those who own or have some interest in apples or pears on which fluorine remains as insecticidal residue. It does not appear from either petition that any petitioner named therein owns or has any interest in such apples or pears.

*[Petitioners Use Cryolite as Insecticide]*

One of the petitioners (No. 10,497)<sup>1</sup> states that apples and pears are produced by some of the petitioners named therein, and that "fluorine spray, namely cryolite," is used as an insecticide on said apples and pears, but it does not state that fluorine remains on any of them, as insecticidal residue or otherwise.

The other petition (No. 10,952)<sup>2</sup> states that apples and pears are grown and shipped by some of the petitioners named therein and are purchased and shipped by one of said petitioners, and that "fluorine in the form of cryolite" is used as an insecticide on said apples and pears, but it does not state that fluorine remains on any of them, as insecticidal residue or otherwise.

The statement that "fluorine spray, namely cryolite," is used on the apples and pears mentioned in No. 10,947 and the statement

that "fluorine in the form of cryolite" is used on the apples and pears mentioned in No. 10,952 may be disregarded, for we know judicially that there is no such thing as "fluorine spray, namely cryolite," or "fluorine in the form of cryolite." Fluorine and cryolite are not the same thing. Fluorine is a gas. Cryolite is a solid. Fluorine is a chemical element. Cryolite is a compound of sodium, aluminum and fluorine ( $\text{Na}_3\text{AlF}_6$ ). Being a compound, cryolite is a distinct substance,<sup>3</sup> which is to say, it is neither sodium nor aluminum nor fluorine.

*[Cryolite Not Mentioned in Order]*

If cryolite is used as an insecticide on the apples and pears mentioned in the petitions, some of it may remain thereon as insecticidal residue. That, however, is immaterial, for the order does not limit or purport to limit the quantity of cryolite so remaining on apples or pears. It says nothing about cryolite.

Since it does not appear that any of the petitioners will be adversely affected by the order, if placed in effect, the petitions should be and are

Dismissed.

<sup>1</sup> As amended on July 15, 1946.

<sup>2</sup> As amended on July 15, 1946.

<sup>3</sup> This is true of all compounds. Examples: Water, a compound of hydrogen and oxygen,

is neither hydrogen nor oxygen, but is a distinct substance. Common salt, a compound of sodium and chlorine, is neither sodium nor chlorine, but is a distinct substance.







# INJUNCTION CASES

## UNITED STATES v. ROYAL LEE, AN INDIVIDUAL DOING BUSINESS AS VITAMIN PRODUCTS COMPANY

United States District Court for the Eastern District of Wisconsin. Civil  
Action No. 546. September 11, 1941. 40 F. Supp. 801.  
Reversed, 131 F. 2d 464. See page 445.

Where, at a pre-trial conference, the parties had entered into a stipulation so that the court should determine whether the complaint stated a cause of action, the allegations of the complaint concerning the falsity and misleading character of defendant's literature were to be deemed to be true.

Sections 302 (a), 502 (a), 502 (e), Federal Food, Drug, and Cosmetic Act.

In an injunction suit under the Act, the Government charged that the defendant caused literature which made false therapeutic claims for defendant's product, but which had been shipped in interstate commerce separately from the product, to be displayed with the product while held for sale. Since the action was brought under the Act, the court was not concerned with false advertising, but was required to determine whether there was a misbranding.

Sections 301 (a), 301 (b), 301 (k), 302 (a), Federal Food, Drug, and Cosmetic Act.

Congress did intend in the Act that labeling should be something more than the printed or written matter actually affixed to the article itself. It undoubtedly had in mind the practice of manufacturers of placing circulars and printed matter in cartons, which literature would not be affixed to the product to be sold.

Sections 201 (m), 301 (k), Federal Food, Drug, and Cosmetic Act.

However, it would be a case of legislation by judicial construction to say that literature "placed on shelves, display counters, or in window displays" comes within the definition of labeling.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

In view of the fact that Congress decided that advertising of food, drugs, and cosmetics was to be handled by the Federal Trade Commission, there is no justification for any court to put a strained and unnatural construction upon the term "labeling."

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

The Act is a criminal one. Criminal statutes are not to be extended by intendment because the court thinks the legislature should have made them more comprehensive.

Title, Federal Food, Drug, and Cosmetic Act.

B. J. Husting, U. S. District Attorney, Milwaukee, Wis., for plaintiff.

Charles Swidler, Milwaukee, Wis., for defendant.

### [*Nature of Proceeding*]

DUFFY, District Judge: This is a civil action wherein the plaintiff seeks an injunction against the defendant under the provisions of the Federal Food, Drug, and Cosmetic Act (Sec. 332, U. S. C., Title 21), for alleged violation of Sec. 331 (a), (b), and (k), Title 21, U. S. C., for shipment of misbranded articles of drug, as defined by Sec. 352 (a) and (e), Title 21, U. S. C.

### [*Question at Issue*]

At the pre-trial conference herein, the parties entered into a stipulation, for the purpose of clarifying the issues, that prior to the trial of this action, the court should determine whether plaintiff's complaint, paragraphs 15 to 24 inclusive, states a claim upon which relief can be granted against the defendant; that is to say, whether the acts alleged in said paragraphs constitute



such acts with reference to a food or drug, while held for sale after shipment in interstate commerce, as are prohibited in Sec. 331 (k), Title 21, U. S. C.

[*Alleged Violations*]

The paragraphs in question allege that the defendant has caused to be written and printed, various circulars, pamphlets, booklets, and other literature making therapeutic claims for the products which are manufactured by the defendant. In particular, the government claims that said literature falsely represents that the products will cure and constitute adequate treatment for a long list of human ailments. It is alleged that such literature is sent in interstate commerce, to agents and distributors of said products, separately from the products to which they relate. It is further alleged that the defendant, by virtue of his power and control over said agents and distributors, requires that they place the separately shipped literature so as to be displayed with the products of the defendant while held for sale. The question to be determined is whether the act of bringing written, printed, or graphic matter containing false and misleading therapeutic claims, in the presence of, proximity of, and in association with an article, after shipment in interstate commerce, is a misbranding of that article within the meaning of the term "misbranding" as that term is defined in the act.

[*Statutory Provisions*]

Sec. 331, Title 21, U. S. C. A. provides:

"The following acts and the causing thereof are hereby prohibited: . . . (k)

The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

Sec. 352 (a) provides that a drug is deemed misbranded if its labeling is false or misleading in any particular. Sec. 321 (m) defines labeling:

"The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

[*Nature of Alleged Misbranding*]

The allegations of the complaint concerning the falsity and misleading character of defendant's literature are, for the pur-

pose of deciding this question, deemed to be true.

Plaintiff admits that the alleged misbranding is not a physical tampering with the labeling, nor a tampering with the product itself. Plaintiff contends that the misbranding occurs through the device of causing written, printed, and graphic matter, containing false and misleading therapeutic claims, to be shipped through interstate commerce separately from the product; and that at the destination, such written, printed, and graphic matter becomes associated with and used in proximity and in the presence of the transported product on the shelves, display counters, and in the window displays on the premises of defendant's agents and distributors.

[*Legislative Intent*]

In determining the intent of Congress, it may be helpful to recall some of the legislative history of the act in question, which at that time was commonly called the "Copeland Bill." The bill, as introduced, gave jurisdiction to enforce same to the Department of Agriculture. It was generally known at that time that the Federal Trade Commission desired to enforce any provisions as to false advertising. While the Copeland Bill was pending, Public Act No. 477 FRD was passed (approved March 21, 1938), which measure specifically gave jurisdiction over false advertising of foods, drugs, and cosmetics to the Federal Trade Commission. Thereafter the Copeland Bill was amended and, as passed (approved June 25, 1938), gave jurisdiction to the Department of Agriculture to enforce the provisions as to adulteration, packaging, and labeling; but the enforcement as to false advertising remained in the Federal Trade Commission. On June 30, 1940, the enforcement of the Federal Food, Drug, and Cosmetic Act was transferred from the Department of Agriculture to the Federal Security Agency.

As this action is brought under the Federal Food, Drug, and Cosmetic Act, we are not here concerned with any false advertising by the defendant. We must determine whether there was a misbranding by false or misleading labeling.

[*Labeling Defined*]

The plaintiff necessarily contends for an extremely broad interpretation of the language of the act defining labeling:

"(m) The term 'labeling' means all la-



bels and other written, printed, or graphic matter . . . (2) accompanying such article."

The government contends that when Congress said "accompanying such article," it did not necessarily mean accompanying in the ordinary sense of the word, as long as the literature eventually came together with the products before or when offered for sale.

Congress did intend that labeling should be something more than the printed or written matter actually affixed to the article itself. It undoubtedly had in mind the practice of manufacturers of placing circulars and printed matters in cartons, which literature would not be affixed to the product to be sold.

[*Advertising Not Labeling*]

However, it would be a case of legislation by judicial construction to say that literature "placed on shelves, display counters, or in window displays" (to use the language of the government) comes within the definition of labeling. It is advertising, pure and simple. The Congress could have provided that all written or printed matter displayed near or in proximity of the article was labeling but it did not do so. Suppose defendant provided a sign, extolling

the virtues of his product, to be hung on the wall? Under the construction contended by the government, it could be considered labeling. What about a billboard across the street? At what point could a line be drawn where labeling would end and advertising begin?

In view of the fact that Congress decided that evils in the field of advertising as to food, drugs, and cosmetics were to be handled by the Federal Trade Commission, and the Copeland Bill was therefore amended accordingly, there is no justification for any court to put a strained and unnatural construction upon the term "labeling". Furthermore, the Food and Drug Act is a criminal statute. In *United States v. Weitzel*, 246 U. S. 533, the Supreme Court stated (p. 543):

" . . . Statutes creating and defining crimes are not to be extended by intentment because the court thinks the legislature should have made them more comprehensive . . . "

To the same effect, see *Walter W. Oeflein, Inc. v. The State*, 177 Wis. 394, 396.

[*Conclusion*]

It is my opinion that paragraphs 15 to 24 inclusive of the complaint do not state a claim against the defendant upon which relief can be granted.

---

UNITED STATES v. ROYAL LEE, AN INDIVIDUAL  
DOING BUSINESS AS VITAMIN  
PRODUCTS CO.

United States Circuit Court of Appeals for the Seventh Circuit. No. 7915.  
November 25, 1942. 131 F. 2d 464.  
Reversing 40 F. Supp. 801. See page 443.

A complaint for an injunction under the Act charged that the defendant had caused to be sent in interstate commerce, to agents and distributors, circulars making false therapeutic claims for defendant's products; and that the defendant required agents and distributors to display the separately printed circulars with defendant's products. The court did not agree with defendant's contention that the word "accompany," in Section 201 (m), did not include literature which did not go along with the product.

Sections 201 (m), 301 (k), 302 (a), Federal Food, Drug, and Cosmetic Act.

Among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates. Misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

Sections 301 (a), 301 (b), 301 (k), 502 (a), Federal Food, Drug, and Cosmetic Act.



The Act was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction.

Title, Federal Food, Drug, and Cosmetic Act.

Congress did not exclude from the definition of "labeling" printed matter which constitutes advertising.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

B. J. Husting, U. S. District Attorney; Carl R. Becker, Assistant U. S. District Attorney; both of Milwaukee, Wis., for the United States.

Charles Swidler, Milwaukee, Wis., for appellee.

Before EVANS, and KERNER, Circuit Judges, and LINDLEY, District Judge.

[Facts of Case]

KERNER, Circuit Judge: This is an appeal from a decree dismissing plaintiff's complaint for an injunction against violations of § 301 (a), (b), and (k) for the shipment of misbranded articles of drug and § 502 of the Federal Food, Drug, and Cosmetic Act of 1938, c. 675, 52 Stat. 1040; 21 U. S. C. A., § 331 (a), (b), and (k) and § 352 (a).

The complaint charged that defendant had caused to be printed circulars making therapeutic claims for the products which he manufactures, falsely claiming that the products will cure and constitute adequate treatment for human ailments; that such circulars were sent in interstate commerce to agents and distributors of said products, separately from the products to which they relate; and that by virtue of defendant's power and control over his agents and distributors, he required them to display the separately shipped circulars with defendant's products.

[Question To Be Decided]

We must decide whether the act of bringing printed matter containing false and misleading therapeutic claims in the presence of, and in association with, an article after shipment in interstate commerce, results in the article being misbranded in violation of § 301 (k) of the Act.

[Statute Involved]

The Federal Food, Drug, and Cosmetic Act, so far as material, provides:

"Sec. 201. For the purpose of this Act—

\* \* \* \* \*

"(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

\* \* \* \* \*

"Sec. 301. The following acts and the causing thereof are \* \* \* prohibited:

\* \* \* \* \*

"(a) The introduction or delivery for introduction into interstate commerce of any \* \* \* drug \* \* \* that is \* \* \* misbranded.

"(b) The \* \* \* misbranding of any \* \* \* drug \* \* \* in interstate commerce.

\* \* \* \* \*

"(k) The alteration, \* \* \* of \* \* \* any part of the labeling of, or the doing of any other act with respect to, a \* \* \* drug, \* \* \*, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

\* \* \* \* \*

"Sec. 502. A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

[Plaintiff's Contention]

In the District Court counsel for plaintiff contended that the phrase "accompanying such article" means that misbranding occurs through any device which causes printed matter containing false therapeutic claims to be shipped through interstate commerce, including printed matter shipped separately from the product, and constitutes a violation of § 201 (m) if at the destination it becomes associated with and is used in proximity to the transported product on the shelves and display counters of the defendant's agents and distributors.

[Holding of District Court]

The District Court, however, was of the opinion that literature "placed on shelves, display counters, or in window displays" was advertising within the meaning of the Federal Trade Commission Act, 15 U. S. C. A § 55, providing that "'false advertisement' means an advertisement, other than labeling," and consequently was not a misbranding of an article in interstate commerce.



[*Interpretation of 1906 Act*]

Section 8 of the Food and Drugs Act of 1906 provided that the term "misbranded" should apply to all drugs, or articles of food, the package or label of which bore any statement, design, or device regarding such article, which was false or misleading in any particular, 21 U. S. C. A. § 9. In interpreting this section, it was held that a circular enclosed with an article inside the carton in which it was offered for sale was not within the purview of this section. *United States v. American etc.*, 186 F. 387. Thereafter, in 1912, the Act was amended, specifically extending the definition to include statements, designs and devices contained in the package, "to hit precisely the case of circulars or printed matter placed inside the package." *Seven Cases v. United States*, 239 U. S. 510, 515. The Act was again amended in 1938 so as to include within the term "labeling," all "labels," and "other written, printed, or graphic matter \* \* \* accompanying such article."

[*Meaning of "Accompany"*]

We have not had the benefit of a brief on behalf of the defendant, but in the District Court the defendant contended that the word "accompany" did not include literature which did not go along with the product—in other words, that the test was not nearness, concurrence of display, or availability for reading. With this contention we cannot agree.

The word "accompany" is not defined in the Act, but we observe that among the meanings attributed to the word are "to go along with," "to go with or attend as a companion or associate," and "to occur in association with," Webster's New International Dictionary (2nd Edition). There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal

construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

[*Legislative History of Act*]

This conclusion is sustained by the legislative history of the Act, from which it appears that it was not the purpose of Congress to limit the scope of the phrase "accompanying such articles" to printed matter placed in the carton in which the article is contained. See Senate Report 1944, 73rd Cong., 1st and 2nd Sessions, and Senate Report No. 493 of the Committee on Commerce, 73rd Cong., 2nd Sess.

[*Research Laboratories Case*]

Our conclusion is also sustained by the decision in the case of *United States v. Research Laboratories*, 126 F. (2) 42, decided after the District Court had dismissed the complaint in the instant case. The defendant in the *Research* case contended that the circulars constituted advertising and did not constitute labeling within the meaning of the Act. In disposing of the contention, the court said, p. 45:

"The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."

The court also said:

"\* \* \* nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey."

[*Reversed and Remanded*]

The decree of the District Court is reversed, and the cause is remanded for further proceedings in conformity with this opinion.



UNITED STATES v. SEKOV CORPORATION AND HAZEL  
RUTH VOKES, TRADING UNDER THE  
NAME OF SEKOV STUDIOS

United States District Court for the Southern District of California. June 12, 1943. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1001) Issued March 1945.

A suit was instituted to restrain defendants from introducing into interstate commerce a reducing preparation containing thyroid, on the ground that it was dangerous to health when used as prescribed in the labeling. The evidence clearly revealed the misbranding charged by the Government.

Sections 301 (a), 302 (a), 502 (j), Federal Food, Drug, and Cosmetic Act.

The record showed that any obese person could obtain the product at defendants' studios without any inquiry as to whether obesity and hypothyroidism were present. Consequently, statements on the carton and in pamphlets that the preparation was a reducer for overweight due to a thyroid deficiency were inadequate to forestall the evil inherent in the use of the preparation by persons whose hypothyroidism had not been established by a competent physician.

Section 502 (j), Federal Food, Drug, and Cosmetic Act.

LEON R. YANKWICH, District Judge: The above-entitled cause heretofore tried and submitted, is hereby decided as follows:

*[Introduction of Sekov Products into  
Interstate Commerce Enjoined]*

Judgment is ordered entered for the plaintiff as prayed for in its complaint, restraining and enjoining the defendants, their servants, agents, officers, employees, attorneys and assigns, and each of them, from the introduction or delivery for introduction into interstate commerce of any of their said products herein before designated and described as "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T," in violation of or contrary to Title 21, U. S. C. A., Sections 301 to 392.

*[Preparation Dangerous to Health]*

I am of the view that the evidence shows clearly that the preparation is misbranded because "it is dangerous to health when used in the dosage or with the frequency or duration prescribed and recommended or suggested in the label thereof." (21 U. S. C. A. Sec. 352 (j).) Even the physicians who testified for the defendants admitted that the use of thyroid extracts in the quantity prescribed by obese persons, whose obesity was not due to hypothyroidism, might prove injurious to health. The physicians who testified for the Government, each of whom is an expert in his field, were em-

phatic in their statement that such use not only might be detrimental, but in all likelihood would be so. If the defendants limited sales to persons who are suffering from obesity due to hypothyroidism — either by requiring a physician's certificate to that effect, or by conducting an examination of the person before making a sale, it could well be contended that, with such precaution, any detrimental results would be only those incident upon any self-medication, which the law does not prohibit. As the sale is not made through general outlets, but through agencies conducted by the defendants—studios located in various cities throughout the United States, such safeguards could easily be enforced. As it is, the record shows that any obese person who calls at one of these studios can obtain the product without any inquiry as to whether the conditions for which the product is intended as a remedy, co-existing obesity and hypothyroidism,—are present. In view of this, the statement on the carton that the preparation is "a reducer for overweight due to a thyroid deficiency" and similar statements in the pamphlet are inadequate to forestall the evil inherent in the use of this preparation by persons whose hypothyroidism has not been established by a competent physician. It is to be noted, as stated by me during the argument, that nowhere is there a warning couched in imperative negatives such as are found in



products which may have a deleterious effect. Nowhere is there a statement "*Do not use this* unless a physician has told you that your obesity is due to hypothyroidism." The reference to the consultation of a physician is ineffective. It reads: "We recommend that you consult physician to determine the cause of your overweight as the use of THYROID by a person not deficient in THYROID may result in serious or irreparable injury to the health of the user."

[*Contra-Indications Are Inadequate*]

I am also satisfied that the contra-indications are inadequate. In the light of the expert testimony, I do not think that the average person seeking to reduce would be competent to detect the evils resulting from its use. Bearing in mind that the defendants in their advertising and literature, appeal especially to the vanity of women, I am of the view that the average woman, in her

desire to achieve a beauty of form, would be more inclined to consider the manifestations of ill effect as the natural price to pay for the results to be achieved. So that if we consider the warnings in relation to the persons to whom they are addressed, as counsel bids us to, it is quite evident that they are ineffective for the purpose.

[On June 25, 1943, the court handed down findings of fact substantially sustaining the allegations in the complaint, and conclusions of law sustaining the prayer of the complaint. On the same day a decree for permanent injunction was filed, ordering the defendants forever restrained and enjoined from introducing or delivering for introduction into interstate commerce any of their products designated and described as "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T."]

---

**UNITED STATES v. SWIFT & COMPANY  
AND H. N. BATES**

United States District Court for the Middle District of Georgia, Macon  
Division. Civil Action No. 216. December 31, 1943. 53 F. Supp. 1018.

In an action by the Government to enjoin defendants from shipping adulterated butter in interstate commerce, it was held that the butter consisted in part of a filthy and decomposed substance and was unfit for food, and that the Government was entitled to an injunction.

Sections 301 (a), 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Congress intended that the word "filthy," as used in the Act, should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

T. Hoyt Davis, U. S. Attorney, Macon, Ga.; Charles W. Walker and Henry S. Barnes, Assistant U. S. Attorneys, Macon, Ga.; for plaintiff.

Neal J. Huff, General Attorney's Office, Swift & Co., Chicago, Ill.; Jones, Jones & Sparks (A. O. B. Sparks and Charles M. Cork of counsel), Persons Building, Macon, Ga.; for defendants.

BASCOM S. DEAVER, District Judge: After having heard the evidence and argument of counsel, I make the following

**Findings of Fact**

1. Swift & Company is a corporation with and office, agency, and place of business in Macon, Bibb County, Georgia.

2. Between October 10, 1940 and December 19, 1942, the Macon, Georgia, branch

of Swift & Company was engaged in manufacturing butter, some of which was shipped in interstate commerce.

3. During said period Swift & Company shipped in interstate commerce butter manufactured from cream, some of which at times had in it rodent hair, feather parts, flies, maggots, and other such filth, and some of which was decomposed and contained mold.



4. The pure and clean cream in the process of manufacture was mixed with the decomposed cream and the cream which contained mold, rodent hair, feather parts, flies, maggots and other such insect filth, and all passed together through the filters, was then pasteurized through the same pasteurizer, held in the same storage vats, and churned together in the same churn.

5. The plant itself is sanitary and the equipment is standard and satisfactory.

6. Some of the butter manufactured from said cream, in spite of filtration through standard filters, contained insect fragments and, in minute quantities, substances which came from broken or partially dissolved insects, and materials which had been a part of the decomposed cream, and mold in such quantities that in ten instances out of fourteen, where the butter was microscopically examined for mold, 100% of the microscopic fields examined by the Wildman Method were found to contain mold.

7. There is a general correlation between the microscopic mold parts found in butter and the quality of the cream from which the butter is produced. The presence of microscopic mold in butter in excessive quantities may be accepted as an indication that the cream from which the butter was made either contained filth or was to an extent decomposed. Mold in butter, therefore, is relevant evidence to be considered along with all the other evidence as to the condition of the cream, but it is not necessary in this case to find just what weight should be given to such evidence.

8. Such butter so produced by Swift & Company at its Macon Plant was filthy and unfit for food.

9. Swift & Company, for a number years, has engaged in a nation-wide program of cream quality improvement and has advocated quality improvement in its dairy products.

10. H. N. Bates, the Macon Manager of Swift & Company during most of 1942, failed to carry out fully the instructions of the management of Swift & Company with regard to the cream quality improvement program in the State of Georgia and the making of mold tests upon the cream from which butter was made at the Macon plant.

11. In October 1942, partially as a result of requests on the part of Swift & Company, the newly organized Dairy Department of Georgia Agricultural College began

to interest itself in a cream quality program within the State of Georgia, and in the latter part of that year, also partially through the efforts of Swift & Company, the Georgia Butter Manufacturers' Association was organized and began to participate in a general program of cream quality improvement within the State.

12. After the inception of such program, experts and other representatives of Swift & Company's Cream Improvement Department did active field work in furtherance of cream quality improvement in Georgia.

13. As a result of all of these efforts, the quality of cream being received at the Macon plant of Swift & Company in the latter part of 1943 and the butter produced during that period showed a marked improvement over that produced at the times referred to in the complaint. The butter now scores 89 and 89½.

14. W. W. Joyner, the present Manager of the Macon plant of Swift & Company, has actively participated in this field work and in the Georgia cream quality improvement program.

15. With a continuation of the work being done by the University of Georgia and the members of the Butter Industry of Georgia, continued improvement in cream quality should result and a higher quality of commercial butter be produced in the State of Georgia, especially if they had the cooperation of the State Agricultural Department. However, it does not appear from the evidence that the State Agricultural Department is taking any active part in the Georgia cream quality program.

16. Cream used at Swift's Macon plant is produced in the main by small producers scattered over a wide area. It is held generally for about a week before it is delivered to the plant. The conditions under which it is produced and held are such that almost inevitably a large part of it will contain insects and become to some extent decomposed. Without the full cooperation of the State Agricultural Department, it is not likely that sufficient pure, clean cream can be had from which to make butter in commercial quantities lawful to be shipped in interstate commerce. If all the cream in the state went to interstate shippers of butter, they could require the production of clean cream simply by rejecting all bad cream. But as long as bad cream subject to be rejected by interstate manufacturers can be



sold to intrastate manufacturers, the cream situation will probably remain bad. At such time as state law, strictly enforced, may require a high standard for cream, no bad cream can be sold in the state and then conditions of production and manufacture will change. Until that time arrives Swift & Company cannot force the production of clean cream by any amount of good faith or effort and, while the cream quality program, if continued, will no doubt improve cream conditions, it will not likely cure them. These findings are made only as touching the necessity for an injunction and as a basis for the exercise of a discretion in granting or denying an injunction.

### Conclusions of Law

#### [Jurisdiction]

1. This Court has jurisdiction of the parties and of the subject-matter of this case.

#### [Meaning of "Filthy"]

2. Congress intended that the word "filthy," as used in the Act, should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition.

#### [Mold in Butter]

3. It is not necessary in this case to adjudicate the legal effect of mold alone in butter.

#### [Adulteration of Butter Not Preventable by Defendant]

4. In spite of the improvement which has been shown in the quality of cream produced in Georgia and of the butter now being manufactured at the Macon plant of Swift & Company, it does not appear from the evidence that, under the present condi-

tions existing in the Georgia Cream Industry, other and further adulterations can adequately be prevented by the defendant, Swift & Company. Particularly may that be true so long as the State Agricultural Department takes no part in the program.

#### [Butter Found to be Filthy, Decomposed and Unfit]

5. The butter referred to in the findings of fact was adulterated within the meaning of Title 21, Sec. 342 (a) (3) in that it consisted in part of a filthy and decomposed substance, and was unfit for food.

#### [Injunction]

6. Plaintiff is entitled to an injunction as prayed.

### Judgment

Wherefore, it is considered, ordered and adjudged that:

1. The defendants, H. N. Bates and Swift & Company, a corporation, all of its officers, representatives, agents, employees and servants, and all persons acting or claiming to act on behalf of or under the defendants, be and they are perpetually enjoined and restrained under the provisions of Sec. 332, U. S. Code, Title 21, from shipping in interstate commerce, in violation of Sec. 331 and Sec. 342 (a) (3), U. S. Code, Title 21, adulterated butter manufactured or to be manufactured in its Macon, Georgia, plant.

2. Jurisdiction of this cause is retained for the purpose of enforcing or modifying this decree, and for the purpose of granting such additional or supplemental relief as may hereafter appear necessary or appropriate.

3. The defendant, Swift & Company, shall pay all costs involved in this proceeding.

This the 31st day of December, 1943.

---

## UNITED STATES v. LAZERE, DOING BUSINESS AS SIOUX CITY BAKERY

United States District Court for the Northern District of Iowa, Western Division. Equity No. 190. September 22, 1944. 56 F. Supp. 730.

On application for temporary injunction by the Government under the Act, it was held that defendant's bakery products consisted in part of a filthy substance and were prepared under insanitary conditions.

Sections 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

In a suit which charges that a food is adulterated because it is filthy and was prepared under insanitary conditions, proof of injury to health is not essential.

Sections 301 (a), 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.



Congress intended that the word "filthy" and the term "insanitary conditions," as used in the Act, should be construed to have their usual and ordinary meaning.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

The fact that a manufacturer is doing "the best he can" to keep his food products clean is no defense under the Act. A party who cannot prepare proper food products under sanitary conditions must cease putting such products into interstate commerce.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Tobias E. Diamond, U. S. District Attorney, Franklin E. Gill, Assistant U. S. District Attorney, both of Sioux City, Iowa; for plaintiff.

Carlos W. Goltz, and Frank J. Margolin, both of Sioux City, Iowa; for defendant.

*[Temporary Injunction Sought]*

HENRY N. GRAVEN, District Judge: Application for temporary injunction under Federal Food, Drug, and Cosmetic Act. In this the United States asks for a temporary injunction against the defendant, Mose A. Lazere, under 21 U. S. C. A. Section 332, 21 U. S. C. A. Section 331 (a) and 21 U. S. C. A. Section 342 (a) (3) and (4). Evidence was presented at some length in behalf of both parties.

*[Nature of Defendant's Business]*

The defendant for some years has been the owner and operator of a wholesale bakery business carried on at 815 West 7th Street, Sioux City, Iowa. The great bulk of his trade is in the State of Iowa. However, he for some years past and at the present time ships about five per cent of his production in interstate commerce. The interstate commerce shipments are made to patrons residing in South Dakota.

*[Facts of Case]*

The defendant for sometime has been the subject of concern to the inspectors under the Federal Food, Drug, and Cosmetic Act. On May 15th and 16th, 1944, Ralph L. Spink, one of those inspectors, inspected the premises. The building in which the defendant's operations are carried on is a one-story building. It includes, among other rooms, a storage room where flour, sugar and salt are stored, and working rooms where the bakery products are prepared. In the storage room that inspector found a large number of sacks of flour which had been gnawed into by rodents, and a large number of which had been contaminated by urine and excreta from the rodents. On a number of sacks of flour were found rodent excreta pellets numbering from one to fifty. A number of sugar sacks had been gnawed

into by the rodents, and in one sack of sugar was found a mouse nest with several baby mice in it. In an elevator used to convey flour several live weevils were found. Cockroaches were found in a can of glucose, and around fifty cockroaches were found in the working room in an unused cooler. In the working room rodent excreta was also in evidence. Cans of fruit and other containers were standing in the work room with covers off and cockroaches were crawling into them. Silver fish bugs were found crawling around the work room. There was a strong odor of sewage in the basement. The general appearance of the work room was unclean. Inspector Spink talked the matter over with the defendant at the time and urged improvement in conditions and made some suggestions. On July 31st, 1944, the premises were again inspected by Inspector Spink accompanied by Inspector Hubbell. While improvement had been made in some of the conditions, yet a new undesirable condition manifested itself in regard to flies. The abandoned cooling system which had contained so many cockroaches had been removed. Part of the walls had been painted. Cockroaches were still running around and bugs were crawling on the floor. Cans containing ingredients were standing open. The presence of rodents in the store room was still indicated. Live worms were found crawling in a recent shipment of flour. The fly situation was serious. In the portion where rolls were made each tray had from two to ten flies on it, and one tray had twenty-five flies on it. In other places flies were congregated in numbers running into the hundreds. There were no fly-traps or fly paper for the lessening of the fly population. It appears that immediately across the alley from the premises is an abandoned barn which is a breeding place for rodents, and



the defendant has and will always have trouble with rodents as long as the barn is allowed to remain there. The defendant has been attempting to get the City of Sioux City to have the barn removed or destroyed. While some steps have been taken by the City towards that end, the barn is still there. It also appears that the defendant has been greatly handicapped in keeping the premises clean because of shortage of help due to war conditions. The Federal Food, Drug, and Cosmetic enforcement agency caused loaves of defendant's bread which had been shipped to South Dakota, to be analyzed. An analysis of two different purchases of defendant's bread made in two different places in South Dakota, showed the presence of rodent hairs and insect fragments.

[*Defendant's Contentions*]

The defendant's contentions in the main are (1) that none of the matters found in the bread are injurious to the health, and that the conditions referred to under which his bakery goods are being produced, are not injurious to health; (2) That he is doing the best he can under the conditions and circumstances.

[*Statutory Provisions*]

In 21 U. S. C. A. Section 331 (a) it is provided:

"The following acts and causing thereof are hereby prohibited:

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

In 21 U. S. C. A. Section 342 (a) (3) and (4), it is provided:

"A food shall be deemed to be adulterated—

"(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

In 21 U. S. C. A. Section 332, it is provided:

"(a) The district courts of the United States \* \* \* shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, as amended, to restrain violations of section 331, except paragraphs (e), (f), (h), (i), and (j)."

[*Opinions Not Numerous*]

There were material changes made in the law by the New Federal Food, Drug, and Cosmetic Act of June 25th, 1938. The provisions of the new act here noted became effective June 25th, 1939, and because of the recent effective date the number of opinions under the new law are not numerous.

[*Injuriousness to Health Need Not Be Proved*]

The defendant strongly contends that it is necessary for the Government to show that the bakery products of the defendant were injurious to the health. The defendant offered medical testimony to the effect that because of the high heat under which bread is baked that the presence of parts of rodents and bugs in the bread would not injure the health. Medical testimony was also offered to the effect that for the same reason the production of bakery products under the filthy conditions heretofore described, would not injure the health. There was further medical testimony that people "could eat mice and not hurt them," and that a person could eat mouse excreta without hurt to health.

It was the rule under the former Federal Food, Drug, and Cosmetic Act that in the case of adulterated food, proof that it was injurious to the health was not essential. *Anderson & Co. v. United States* (9th Cir. 1922), 284 F. 542; *United States v. Two Hundred Cases of Adulterated Tomato Catsup* (D. C. Oregon, 1914), 211 F. 780; *United States v. Two Hundred Cases, more or less of Canned Salmon* (D. C. Texas, 1923), 289 F. 157. Since the new Act is more stringent as to filthy food than the old act, the defendant's contention that the Government must show that the food in question is injurious to the health cannot be sustained. In the recent case of *United States v. Swift & Co.*, (D. C. Georgia, 1943), 53 F. Supp. 1018, having to do with the meaning to be given to the word "filthy" found in 21 U. S. C. A. Sec. 342 (a) (3), on page 1020 of the opinion it is stated:

"Congress intended that the word 'filthy,' as used in the Act, should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition."

[*"Insanitary Conditions" Construed*]

It would also seem plain that the term "insanitary conditions" used in 21 U. S.



C. A. Sec. 342 (a) (4), should also be construed to have its usual and ordinary meaning."

*[Products Held Filthy and Conditions Held Insanitary]*

It is the holding of the Court that the bakery products in question did consist of a "filthy" substance under 21 U. S. C. A. 342 (a) (3), and were prepared under "insanitary conditions" under 21 U. S. C. A. 342 (a) (4).

*[Inability of Defendant To Avoid Insanitary Conditions No Defense]*

It is the claim of the defendant that he should not be enjoined from shipping his bakery products in interstate commerce because he is doing the best he can in view of the difficulty of securing help and in view of the difficulties caused by the abandoned barn in the matter of the rodent problem. While the situation in which the defendant

finds himself can be sympathetically understood, yet it would not be good law or good sense to permit a person to put filthy food substances into interstate commerce, or to permit a person to prepare food for such purpose under insanitary conditions. The Federal Food, Drug, and Cosmetic Act does not provide that parties shall avoid doing such things if it is possible, it provides that it shall not be done at all. A party who cannot prepare proper food products under sanitary conditions must cease putting such products into interstate commerce. It is obvious that in the instant case the defendant cannot comply with the Federal Food, Drug, and Cosmetic Act without a drastic rehabilitation of his premises, and that until such drastic rehabilitation is made that he should be enjoined from shipping or offering to ship in interstate commerce bakery products prepared on the premises in question.

## UNITED STATES v. SAUNDERS MILLS, INC., CLARENCE M. SAUNDERS, AND EVELYN M. CROW

United States District Court for the Southern District of Ohio. December 7, 1944. Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8587) Issued July 1946.

A suit was instituted to enjoin defendants from introducing into commerce alfalfa meal which contained a smaller amount of protein and a larger amount of crude fiber than were declared on the labels. Defendants sought to strike recitals of criminal and condemnation proceedings and the results thereof. As to the various pleas of guilty, and the admission of the allegations of the libel in a condemnation suit, such allegations are relevant and material.

Sections 301 (a), 302 (a), Federal Food, Drug, and Cosmetic Act.

Where allegations of pleas and admissions constituted a pleading of evidentiary facts rather than ultimate facts, the court felt a motion to strike should be granted only when the allegations had no relation to the controversy, and when a failure to strike would prejudice the adverse party.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.

The inclusion of evidentiary matter which tends to give a fuller understanding of the complaint is not objectionable.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.

*[Nature of Proceeding]*

FRANK L. KLOEB, District Judge: This is an action brought by the plaintiff for the purpose of obtaining an injunction restraining the defendants from violating the provisions of the Federal Food, Drug, and Cosmetic Act by placing in interstate commerce alfalfa meal products which are alleged to be misbranded. The defendant corporation has filed a motion to strike cer-

tain allegations of the complaint on the ground that the same are "redundant, immaterial and impertinent to the cause of action," and the individual defendants have filed a similar motion to strike the same allegations on the ground that they are "redundant, immaterial and impertinent as to each of said defendants."

*[Defendants' Contentions]*

The matters sought to be stricken are



recitals of criminal proceedings, condemnation proceedings and the results thereof, brought against the defendant corporation. The complaint alleges that, as to the criminal proceedings, pleas of guilty were entered at various times, and in one instance a plea of *nolo contendere*. It is alleged that, in one condemnation proceeding, the defendant admitted the allegations of the libel. The defendants contend that "an adjudication in a criminal case is not an adjudication in a civil action concerning the same transaction," and that a plea of *nolo contendere* is limited to the case in which it is made, is not an admission for any other purpose, and a judgment rendered thereon is not an adjudication for any other purpose. The plaintiff admits that this latter contention of the defendants is probably well taken.

[*Evidentiary Matter Not Objectionable*]

As to the various pleas of guilty, and the admission of the allegations of the libel in the condemnation suit, it is to be noted that such allegations are certainly relevant and material. The real objection to them is that they constitute a pleading of evidentiary facts rather than ultimate facts. While it is true that a judgment in a criminal prosecution cannot be received in evidence in a civil action to establish the truth of the facts on which it was rendered, there is a well recognized exception that a plea of guilty may be received in evidence as a deliberate declaration or admission against interest. In 23 Ohio Jurisprudence, page 995, quoted by the defendant, it is stated " \* \* \* a plea of guilty to a criminal charge may be received in a civil action as an admission against interest \* \* \*."

It is a general rule, also, that admissions by a defendant in an answer in a civil proceeding are admissible, if relevant, in subsequent proceedings between the same parties. 20 American Jurisprudence, Section 644, page 543, 90 ALR, page 1597. The allegations objected to are, therefore, clearly relevant and material, but do constitute the pleading of evidentiary facts.

Under the Federal Rules of Civil Procedure, a pleading should be construed in the light of Rule 1 "to secure a just, speedy, and inexpensive determination of every action \* \* \*." The provisions of Rule 12 (f) do not require the Court to strike allegations of evidentiary facts, and while it may be contended that allegations of evidentiary

matter do not constitute "a short and plain statement of the claim" and do not make the pleading "simple, concise, and direct \* \* \*," as required by Rule 8 (a) (c-1), the Court feels that a motion to strike should be granted only when the allegations have no relation to the controversy, and when a failure to strike will prejudice the adverse party. *Groves v. Paden City Glass Mfg. Co.*, 2 FRD 300; *Sinaiko Bros. Coal & Oil Co., et al. v. Ethyl Gasoline Corp., et al.*, 2 FRD 305. It is particularly true, also, that the inclusion of evidentiary matter which tends to give a fuller understanding of the complaint is not objectionable. *Groves v. Paden City Glass Mfg. Co., supra*; *Sinaiko Bros. Coal & Oil Co., et al. v. Ethyl Gasoline Corp., et al., supra*.

[*Conclusions*]

For the reasons stated above, specification 1 of the defendant corporation's motion is overruled, except that there is ordered stricken from Article VII the last clause thereof beginning "and the defendant corporation was fined," etc. What disposition was made of the matter after a plea of guilty is immaterial in this case.

Specification 2 of the defendant corporation's motion is sustained.

Specification 3 of the defendant corporation's motion is overruled.

Specification 4 of the defendant corporation's motion is overruled, except that there is ordered stricken the last clause of Article IX beginning "and thereafter and on October 13, 1941, a judgment of condemnation was entered," etc.

Specifications 5, 6, 7 and 8 of the defendant corporation's motion are sustained, except that the plaintiff may allege the one instance in which a plea of guilty was entered.

The motion of the individual defendants is overruled *in toto*. It is permissible to join the corporation and its officers in an action for injunction, and no objection has been made to such joinder. The allegations complained of pertain to the defendant corporation and will be so limited at the trial.

The complaint may be amended by interlineation, if desired. The defendants shall file their answer within fifteen (15) days after the complaint is amended.



[The complaint was accordingly amended on February 24, 1945, and the defendant, Saunders Mills, Inc., having consented to the entry of a decree, judgment was entered dismissing the complaint against Clarence

M. Saunders and Evelyn M. Crow, and permanently restraining Saunders Mills, Inc., and its officers and employees from shipping in interstate commerce any misbranded alfalfa animal feed.]

UNITED STATES *v.* G. FRED OBRECHT, INDIVIDUALLY,  
AND TRADING UNDER THE FIRM NAMES HOOD  
MILLS CO., EGG-O-MILK CO., P. FRED'K  
OBRECHT AND SON, FARMERS SER-  
VICE BUREAU, GERARD MILK  
PRODUCTS CO., MILK-  
MALT CO. AND  
OBRECHT  
SALES  
CO.

United States District Court for the District of Maryland. July 25, 1945.  
Notices of Judgment under the Federal Food, Drug, and Cosmetic Act,  
Foods (No. 8894) Issued February 1947.

A suit was instituted to restrain the introduction into interstate commerce of animal feed called "Egg-O-Milk" on the ground that it was misbranded since the name suggested the presence of milk and eggs in substantial quantities, etc., whereas the product contained only insignificant quantities of such products. The Government was entitled to an injunction with respect to the use of the words "Egg-O-Milk" since there was not a sufficient content of either milk or eggs to justify emphasizing such reference to either.

Sections 301 (a), 302 (a), 403 (a), 403 (b), Federal Food, Drug,  
and Cosmetic Act.

The injunction should extend to the prohibition of the use of the trade name "Egg-O-Milk" in connection with the sale of the product but should not prohibit any reference to eggs or milk in the list of ingredients. However, the statement in the list of ingredients to milk and eggs should be qualified by some phrase such as "in small amounts."

Sections 302 (a), 403 (a), 403 (b), Federal Food, Drug, and Cosmetic  
Act.

#### Findings of Fact

COLEMAN, District Judge: I. That the defendant, G. Fred Obrecht, has been for many years, and now is, trading and doing business individually, and under the assumed names and styles of Hood Mills Co., Egg-O-Milk Co., P. Fred'k Obrecht & Son, Farmers Service Bureau, Gerard Milk Products Co., Milk-malt Company, and Obrecht Sales Co., and is now, and has been for many years, engaged in the business of manufacturing, mixing, blending, packaging, selling, marketing, and shipping in interstate commerce animal feeds, foods within the meaning of Section 201 (f) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 321 (f)]; and that the said defendants conduct business at

4101 E. Monument Street, Baltimore, State of Maryland, and at Hoods Mills, Carroll County, State of Maryland, within the jurisdiction of this Court, and have been so located and engaged in said business for a number of years.

II. That during the period, and on or about and between December 1, 1931 and March 26, 1945, the defendant, G. Fred Obrecht, individually, and trading under the assumed names and styles aforesaid, introduced and delivered for introduction into interstate commerce at various times and in varying amounts, addressed to consignees in different states of the United States, an animal feed known as "Egg-O-Milk. The Perfect Food—Protein 18%," which name was contained on the labels on the con-



tainers of the said animal feed, and which is hereinafter referred to as "Egg-O-Milk."

III. That the said animal feed "Egg-O-Milk" is a blended poultry food containing a very small amount of milk and egg, and that there is not a sufficient content in the said feed of either milk or egg to justify reference thereto by use of the name "Egg-O-Milk."

IV. That the defendants do not manufacture or distribute any products or animal feeds with a substantial egg or milk content, and that the trade-name "Egg-O-Milk" is used by the defendants for no other purpose than in connection with the marketing of this particular product.

V. That the labeling of the said product "Egg-O-Milk" is false and misleading in that it represents, suggests, and implies that the said food contains a substantial amount of egg and milk when, in fact, the said food contains only very small and insignificant amounts of egg or milk.

VI. That the defendants have offered the said product for sale under the names of other foods, to wit, egg and milk, although the said product contains only very small and insignificant amounts of either egg or milk.

VII. That the name "Egg-O-Milk Co.," under which defendant G. Fred Obrecht offers the said product "Egg-O-Milk" for sale, and which he uses on his letterheads and in his correspondence with customers, is false and misleading, since the name of the said company represents, implies, and suggests the presence of milk and egg in substantial quantities in the said product "Egg-O-Milk," and is false and misleading in the same manner as the name of the product "Egg-O-Milk" on the labels thereof.

VIII. That the defendant, G. Fred Obrecht, trading as Milkmaid Company and Gerard Milk Products Co. prior to March 17, 1945, introduced into interstate commerce an animal feed known as "Milkmaid Co.'s Blend," a food within the meaning of Section 201 (f) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 321 (f)].

IX. That the label on the container of the said product states that milk and buttermilk are contained therein, but, as a matter of fact, the said product "Milkmaid Co.'s Blend," contains no milk or buttermilk. That the name "Milkmaid Co.'s Blend" on the label of the said product expressly and by implication represents, suggests, and im-

plies, that milk is a substantial ingredient of the said product; that the contents of the said product do not justify any reference to milk as an ingredient thereof by use of the name "Milkmaid Co.'s Blend," or in any other way.

X. That the defendants do not manufacture, market, or distribute any products or animal feeds with a substantial milk content, and that the trade name "Milkmaid Co.'s Blend" is used by the defendants for no other purpose than in connection with the marketing and distribution of this particular product.

XI. That the labeling of the said product known as "Milkmaid Co.'s Blend" is false and misleading in that it represents, suggests, and implies that the said food contains a substantial amount of milk, when, in fact, the said food contains no milk.

XII. That the defendants have falsely offered the said product for sale under the name of another food, to wit, milk, although the said product contains no milk.

XIII. That the names "Milkmaid Company" and "Gerard Milk Products Co.," under which defendant, G. Fred Obrecht, offers for sale and markets the said product "Milkmaid Co.'s Blend," and which he uses on his letterheads and in his correspondence with customers, are false and misleading, since the names of the said companies represent, suggest, and imply the presence of milk in substantial quantities in the said product "Milkmaid Co.'s Blend," and are false and misleading in the same manner as the name of the product "Milkmaid Co.'s Blend" on the labels thereof.

XIV. That the names of the aforesaid products, to wit, "Egg-O-Milk" and "Milkmaid Co.'s Blend," and the names of the companies, to wit, "Egg-O-Milk Co.," "Milkmaid Company," and "Gerard Milk Products Co.," are descriptive of the said products, and are used for no other purpose than in connection with these particular products and the marketing thereof. That there is not a sufficient content of milk and egg, or either of them, in the said products respectively, to justify reference to either milk or egg in the labeling thereof, or in the names of the companies under which they are marketed.

XV. That the protection of the public requires the elimination from the labeling of the said products, and from their trade-names, "Egg-O-Milk" and "Milkmaid Co.'s Blend," and from the names of the said



companies "Egg-O-Milk Company" "Milk-malt Company," and "Gerard Milk Products Co.," of any and all references, express or implied, to milk and egg, or either of them, or to the use by the defendants of the names "egg" or "milk" in connection with the said products or their marketing, or as part of either a firm name, trade name, or label, except as items on the list of ingredients, stating in limiting and definitive language the extent to which they are actually contained therein.

On the basis of the foregoing, the court makes the following

### Conclusions of Law

A. That the defendants have introduced and delivered for introduction, into interstate commerce, in violation of Section 301 (a) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 331 (a)] misbranded animal feed products, known as "Egg-O-Milk" and "Milk-malt Co.'s Blend," foods within the meaning of Section 201 (f) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 321 (f)].

B. That the said foods were and are misbranded within the meaning of Sections 403 (a) and (b) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 343 (a) and (b)] in that the labeling on the said foods was and is false and misleading, and in that they were and are offered for sale and marketed under the names of other foods.

C. That the plaintiff is entitled to a decree of injunction, permanently enjoining and restraining the defendants under the provisions of Section 302 (a) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 332 (a)] from violating the provisions of Section 301 (a) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 331 (a)] and from introducing or delivering for introduction into interstate commerce foods any animal feeds misbranded within the meaning of Sections 403 (a) and (b) of the Federal Food, Drug, and Cosmetic Act [Title 21 U. S. C. Section 343 (a) and (b)]; and from using the words "milk" or "egg," singly or in combination, in the trade-names of the said foods, upon the labels thereof, or in the names of the companies or firms manufacturing, selling, marketing, and/or distributing the said foods, except that the defendants may use the said words in the list of ingredients of the product heretofore designated as "Egg-

O-Milk," provided that the said words "egg" and "milk" are limited, modified, and described by language indicating that the content of "egg" and "milk" as ingredients in the said product is small and of insignificant amount."

### Opinion

This is an injunction proceeding brought by the Government under Section 302 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. Secs. 301-392).

By the weight of the credible evidence, the Government is clearly entitled to a permanent injunction with respect to the use by the defendant of the words "Egg-O-Milk" either as part of a company or trade name; as part of the label on his product, which is a blended poultry food, whether its use precedes or follows the list of ingredients and the statement as to the protein, fat and fibre content of the product; as descriptive of the product, or for any other purpose, because it has been clearly demonstrated that there can be no other purpose in using the words "Egg-O-Milk" except in connection with this one particular product, and there is not a sufficient content of either milk or eggs to justify emphasizing such reference to either. In other words, the Government is entitled to such injunctive relief because there has been a misbranding within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. Sec. 343 (a) and (b)) by (1) use of the words "Egg-O-Milk" as part of the label of defendant's product, and (2) use of these words in connection with the sale of defendant's product.

If it had been shown that other products, having a substantial egg or milk content, or both, were manufactured or distributed by the Egg-O-Milk Company or its affiliates, the situation might be different, and the Government might not be entitled to as broad a decree, but there is not a scintilla of evidence in the case that this trade name, "Egg-O-Milk," is used for any other purpose than in connection with the marketing of this particular product. Indeed, the letter and the statement in the letter in evidence from the defendant in and of itself fully supports the conclusion that the term is directly misleading as applied to his product.

The further question arises: should the injunction extend not merely to the prohibition of the use of the trade name, "Egg-O-Milk," on the labels and otherwise in connection with the sale of this product, but



include as well the prohibition of any reference to eggs or milk in the list of ingredients? I think the answer is "no." Neither the Act nor the Regulations promulgated thereunder require that the ingredients of a product shall all be set out in their actual proportions. It is sufficient if they are enumerated in reasonably accurate, general terms. They need not be put down alphabetically or in the order of their percentages. The amount of proteins, fat and fibre, however, is required to be specifically stated. That has been done here, and I understand there is no dispute in that regard. In other words, the most that the Government is entitled to, in addition to the entire elimination of the use of the words "Egg-O-Milk," is a modification of the label, permitting the inclusion of the word "egg" or "milk," if milk, skimmed milk, powdered egg, powdered egg yolk, etc., are in fact among the ingredients, but only in such manner as to make it clear that those ingredients are contained in small amounts. So I shall require that the list of ingredients as part of the label be redrawn and the words "buttermilk, skimmed milk, powdered egg yolk" be qualified by the words, after each of them: "in small amounts"; or by some phrase at the end, such as: "and small amounts of milk and egg, or milk and egg products." This seems to be fully justified by the weight of the credible evidence which is to the effect that, at most, none of the samples have shown more than a very small percentage—one per cent or one-half of one per cent,—of milk or egg content.

The defendants have introduced no analysis by chemists to offset the analyses introduced by the Government. There is nothing to indicate that the Government's testimony is not entirely trustworthy or accurate. Therefore, we believe that the Government has made out a clear case for an injunction as respects the label as well as respects the use of the trade name generally. Section 403 (a) and (b) of the Act (21 U. S. C. A. Sec. 343 (a) and (b)) declares that "A food shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular. (b) If it is offered for sale under the name of another food." The same applies to the use of the words "Milkmaid" by the Milkmaid Company, because although malt appears to be one of the important ingredients of defendant's blended food product known as "Milkmaid Co.'s Blend," the prefix "milk" causes the same sort of misbranding as does the

use of the words "Egg-O-Milk." We believe nothing more need be said to show the labeling in both instances is clearly false and misleading. Likewise, if the defendant offers his products for sale, and refers to them by his trade names, on his letter-heads or in his correspondence with customers or prospective customers, as "Egg-O-Milk" or "Milkmaid," he is, in effect, misleading the public in the same manner as though he were offering his products "for sale under the name of another food" within the prohibition of the statute, as just quoted.

The position of the Government is sound. The very fact that the defendant has seen fit to operate, not merely through one company, but through seven different companies for the purpose of marketing his products and ringing the changes on the use of the words "milk" or "egg," shows an attempt to play up something which, on the evidence in this case, is non-existent. The granting of an injunction in a case of this character under Section 302 (a) of the Act (21 U. S. C. A. Sec. 332 (a)) is not dependent upon whether somebody has been actually harmed or deceived; it depends upon whether (1) the labeling and (2) offering for sale are false and misleading. Prevention is the basis of the relief afforded,—protection of the public against being deceived or misled.

I may add, finally, that I trust there will not follow in this case what follows in a number of these cases and is quite common in ordinary trade-mark cases, namely, that in spite of what the Court says, the parties come back to the Court, asking to be told what they can do. One side says he didn't think the Court said this or that could be done, and the other side says he thinks the Court did say that it could be done. It is not the province of the Court to tell this defendant precisely what name he shall use, nor is it necessary or appropriate for the Court to give him a list of names. As to a new name, it must be clear from what has just been said that, impliedly, the injunction shall prohibit the use of any new name which embodies the words "Egg-O-Milk," "egg," "eggs," or "milk," as long as the defendant does not deal in any other product that has any egg or milk content. If he should, at some future time, manufacture or deal in an entirely new product, that might be a different matter. But as to what name to use now, that is something that the defendant ought to be able to determine in harmony with this decision.



To summarize and conclude: the injunction runs to the prohibition, under existing circumstances, of the use in any way whatsoever in connection with the marketing of defendant's products, of the words "Egg-O-Milk," "Milkmaid," "eggs," "egg" or "milk" as part of either a firm name, trade name, or label; except that the word "eggs," "egg" or "milk" may be used on labels and otherwise as part of the bona fide description of the egg or milk content of defendant's products, provided such use is qualified by words or phrases indicating the extent, at least in general non-misleading terms, of such content. Any other use of these words in connection with defendant's products

would be, in essence, a deception and would be part and parcel of the misbranding. In other words, if defendant shall no longer be permitted to fill an order for "Egg-O-Milk" or "Milkmaid" without re-labeling the products as herein explained, it certainly follows that, unless and until he in fact produces or deals in substantially different milk or egg products, he ought not to be allowed to write, or to otherwise hold himself out as though he dealt in "Egg-O-Milk" or "Milkmaid," which clearly implies a product having a substantial milk or egg content, or both.

I will sign an order in accordance with the opinion just rendered.

### SAMUEL RUBENSTEIN v. UNITED STATES

United States Court of Appeals for the District of Columbia.

No. 8983. January 14, 1946. 153 F. 2d 127.

The local District of Columbia Act "To prevent the sale of unwholesome food in the District of Columbia" does not, as does the Federal Food, Drug, and Cosmetic Act, cover manufacture as well as sale, or food which is "adulterated" without being "unwholesome or unfit for use."

Sections 201 (b), 301 (a), 301 (g), 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

Even if the provisions of the Federal Act were closely paralleled by local law, it would not follow that the local law would supersede the Federal Act instead of supplementing it. The intent of Congress is clear, both in the Federal Act and local law, that all provisions of the former statute should be enforced in the District of Columbia.

Sections 201 (b), 301 (a), 301 (g), 402 (a), Federal Food, Drug, and Cosmetic Act.

Harry S. Wender, with whom H. Nathaniel Blaustein was on the brief, for appellant.

Sidney S. Sachs, Assistant U. S. Attorney, with whom Edward M. Curran, U. S. Attorney, and Daniel B. Maher, Assistant U. S. Attorney, were on the brief, for appellee. Charles B. Murray, Assistant U. S. Attorney, also entered an appearance for appellee.

Vernon E. West, Corporation Counsel, and Chester H. Gray, Principal Assistant Corporation Counsel, by leave of court, filed a brief on behalf of the Commissioners of the District of Columbia; *amici curiae*.

Before EDGERTON, WILBUR K. MILLER, and PRETTYMAN, Circuit Judges.

#### [Nature of Appeal]

EDGERTON, Circuit Judge: This appeal is from a decree which restrains appellant, a Washington baker, from manufacturing or introducing into commerce in the District of Columbia "any food that consists in whole or in part of filthy or putrid substances or has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth." The court found that appellant had been

doing these things. Appellant does not question the findings. His contention is that because his business is a local one, carried on entirely within the District of Columbia, the Federal Food, Drug, and Cosmetic Act<sup>1</sup> under which action was brought by the United States does not apply.

#### [Specific Sections of Federal Act Quoted]

Section 331 of the Federal Act prohibits "(a) the introduction . . . into interstate

<sup>1</sup> June 25, 1938; 52 Stat. 1040, U. S. C. Title 21 §§ 301-392.



commerce of any food . . . that is adulterated . . . (g) The manufacture within any Territory of any food . . . that is adulterated . . .” Section 321 defines “Territory” as “including the District of Columbia” and defines “interstate commerce” as “(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory . . .” Section 342 provides that food shall be deemed “adulterated . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” With exceptions not material here, section 332 gives the district courts jurisdiction to restrain violations of section 331.

*[Appellant's Premise for Attack Upon Decree]*

On their face the quoted provisions of the Federal Act support the decree appealed from. Appellant's attack upon the decree rests on the premise that these provisions of the Federal Act “parallel in substantially every respect the local laws and regulations upon this subject of adulterated foods.” From this premise appellant derives the conclusion that the Federal Act, despite its plain language, is not applicable to local business in the District of Columbia.

*[Appellant's Premise and Conclusion Found Incorrect]*

We find that both appellant's premise and his conclusion are incorrect.

*[Provisions of District of Columbia Code Set Forth]*

Chapter 1 of Title 33 of the District of Columbia Code forbids sale or delivery, or possession for sale, of “any article of food or drug which is adulterated within the meaning of this chapter.”<sup>2</sup> It does not expressly cover manufacture. It covers only specified kinds of food. These include bread, but do not appear to include the other

bakery products to which the Federal Act, the evidence against appellant, and the injunction relate. This local act defines bread as “adulterated . . . if there is any addition of alum, sulphate of copper, borax, or sulphate of zinc, or other poisonous or harmful ingredient, and if it contains more than thirty-one per centum of moisture, more than two per centum of ash, and less than six and twenty-five one-hundredths per centum of albuminoids.”<sup>3</sup> This language appears to be aimed at deliberate adulteration rather than carelessness and filth. This is made clearer by a proviso that no offense is committed if the purchaser's “order calls for an article . . . inferior to such standard, or where such difference is made known by being plainly written or printed on the package.” No one contends that appellant deliberately inserted in his goods the filth and rodents which they were proved to contain. Moreover the ingredients named in the local act are vastly different from the filthy and putrid substances named in the Federal Act.

*[Local Act of 1941 Cited]*

The local act of December 16, 1941, “To prevent the sale of unwholesome food in the District of Columbia,”<sup>4</sup> forbids sale of any food which is “unwholesome or unfit for use.” It does not, as the Federal Act and the injunction do, cover manufacture as well as sale. It does not, as they do, cover food which is “adulterated” without being “unwholesome or unfit for use.”

*[Local Act and Federal Act Compared]*

It is not clear that these local acts prohibit, as the Federal Act does, all of the misconduct which appellant has committed and which the injunction forbids. Moreover these local acts do not specifically provide, as the Federal Act does, for restraint of such misconduct by injunction. The remedies provided by the local acts are condemnation of unwholesome food, criminal prosecution, and revocation of licenses.<sup>5</sup> Revocation of a license is a drastic remedy which prevents proper operations as effectively as improper ones. Criminal convictions for commercial carelessness are rare, and the maximum penalty on conviction

<sup>2</sup> D. C. Code, 1940, § 33-101; 30 Stat. 246.

<sup>3</sup> § 33-103 (b) ninth.

<sup>4</sup> D. C. Code, 1940, Supp. IV §§ 22-3416 to 22-3422; 55 Stat. 807.

<sup>5</sup> Bakeries are licensed under the General License Law of the District of Columbia. D. C.

Code, 1940, §§ 47-2301, 47-2327; 47 Stat. 550, 554. This law authorizes the Commissioners to revoke licenses in the interest of health, and provides for criminal prosecutions. Code, §§ 47-2345, 47-2346; 47 Stat. 563.



under the local acts is a fine of \$300 or imprisonment for 90 days.<sup>6</sup> An injunction is a relatively simple matter and carries with it a prospect of contempt proceedings if the forbidden acts are continued.

*[All Provisions of the Federal Act To Be Enforced in District of Columbia]*

We conclude that the provisions of the Federal Act which are involved in this case are not closely paralleled by local law. But even if they were, it would not follow that the local law would supersede the federal instead of supplementing it.<sup>7</sup> When a subject is covered both by a general law which does not mention the District of Columbia and by a local law which provides expressly for the District, a question may arise as to whether Congress did or did not have the District in mind in enacting the general law.<sup>8</sup> But when a general law expressly mentions the District, as the Federal Food, Drug, and Cosmetic Act does, it can hardly be contended that Congress did not have the District in mind when it passed the law.<sup>9</sup> Congress has "followed its usual policy

of extending legislation based on the commerce power to the same substantive acts taking place wholly within the District."<sup>10</sup> And in order to preclude any possibility that the local act of 1941, "To prevent the sale of unwholesome food in the District of Columbia," might be interpreted as exclusive, Congress expressly provided that the local Act "shall in no respect be considered as a repeal of any of the provisions of the Federal Food, Drug, and Cosmetic Act, but shall be construed as supplementary thereto."<sup>11</sup> Congress could hardly have expressed more clearly its continuing intention that all provisions of the Federal Act should be enforced, in accordance with their terms, in the District of Columbia. The Commissioners of the District, as *amici curiae* in the present proceeding, express the opinion that the public will be best protected by the combined efforts of the federal and the District food inspection services. Congress appears to have taken the same view.

Affirmed.

## UNITED STATES v. PADDOCK

United States District Court for the Western District of Missouri, Western Division. No. 4166. June 21, 1946. 67 F. Supp. 819.

Later opinion, 68 F. Supp. 407. See page 463.

The Federal Food, Drug, and Cosmetic Act, designed to protect the health of the public, should be liberally construed to effectuate the purpose of Congress.

Title, Federal Food, Drug, and Cosmetic Act.

Advertising matter designed to serve as labeling may serve the twofold purpose of advertising and labeling. The provisions of the law cannot be evaded by placing the labeling matter in the hands of a prospective purchaser in advance of the purchase.

Sections 201 (m), 301 (a), 302 (a), Federal Food, Drug, and Cosmetic Act.

There is no conflict of jurisdiction between the Federal Trade Commission and the courts. The courts have jurisdiction over the labeling function, whereas the Commission would have jurisdiction over the circulars involved in the instant case because of its advertising function.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

<sup>6</sup> D. C. Code, §§ 22-3421, 47-2347.

<sup>7</sup> *Nuckols v. United States*, 69 App. D. C. 120, 99 F. 2d 353. Cf. *Page v. Burnstine*, 102 U. S. 664.

<sup>8</sup> *Johnson v. United States*, 225 U. S. 405, 413 32 S. Ct. 748, 56 L. Ed. 1142; *Kleindienst v. United States*, 48 App. D. C. 190, 202; *O'Brien v. United States*, 69 App. D. C. 135, 99 F. 2d 368.

<sup>9</sup> *United States v. Beach*, 324 U. S. 193.

<sup>10</sup> *Ibid.*, p. 195. The Pure Food and Drugs Act of 1906, 34 Stat. 768, was repeatedly held to be applicable, according to its terms, to local activity in the District. *Galt v. United States*, 39 App. D. C. 470; *Dade v. United States*, 40 D. C. 94. It was also held to supersede certain provisions of an earlier local law. *District of Columbia v. Coburn*, 35 App. D. C. 324.

<sup>11</sup> D. C. Code, § 22-3422.



Letter-ruling by Judge Albert L. Reeves

June 21, 1946

Mr. Charles Rowan

Attorney at Law

229 E. Wisconsin Avenue

Milwaukee, Wisconsin

Honorable David A. Thompson

Assistant U. S. Attorney

Kansas City, Missouri

Gentlemen:

In re: *United States v. Paddock*, No. 4166—

[*Nature of Proceeding*]

Pursuant to our arrangement, I have examined the authorities on the motion to dismiss, or, in the alternative, to strike certain averments of the complaint, and have reached the following conclusion:

[*Literature Could Be Both Advertising and Labeling*]

The Food & Drug Act, designed to protect the health of the public, should be liberally construed to effectuate the purposes of the Congress. The literature and advertising matter covered by the motion was obviously designed by the defendant to serve as a labeling of his product. It had that unquestioned purpose. Under the decisions, such advertising matter may serve the two-fold purpose of advertising and, at the same time, labeling. The provisions of the law could not be evaded by first placing the advertising and labeling matter in the hands of a prospective purchaser in advance of the purchase. It was the Congressional purpose to prevent fraud on the public. The usual and practical method of the producer

was to send the labeling and advertising matter along with the product so that both would reach the purchaser at the same time. The identical result could be reached by sending the labeling matter in advance, or even subsequently. When both of them finally reached the consumer, there was the deception that the law seeks to prevent.

If the law is as contended by the defendant, then the whole purpose of the law could be defeated by placing in the hands of the consumer, through separate channels, the labeling matter and the product. Such evasions could not be permitted.

[*No Conflict Between Federal Trade Commission and Courts*]

There is no conflict of jurisdiction between the Federal Trade Commission and the Court, as indicated in *United States v. Research Laboratories*, 126 F. 2d 42, 1, c. 45. Advertising and labeling circulars may be the same and yet perform the two offices of advertising and labeling. The courts have jurisdiction over the labeling function, whereas the Federal Trade Commission would have jurisdiction at the same time over the same circular because of its advertising function.

The motion to dismiss, or, in the alternative, to strike, should be and will be overruled.

Trusting this may give you the desired information, and with kindest and best wishes to each of you, I am,

Sincerely yours,

ALBERT L. REEVES

---

UNITED STATES v. PADDOCK

United States District Court for the Western District of Missouri, Western Division. No. 4166. September 28, 1946. 68 F. Supp. 407.

Earlier opinion, 67 F. Supp. 819. See page 462.

The Government sought to enjoin defendant from introducing into interstate commerce a drug which was alleged to be misbranded because its labeling contained false therapeutic claims. Literature which was regularly sent through the mails either with the drug or prior or subsequent thereto, which came into the hands of purchasers, and which was intended by the defendant to be used in connection with the treatment advised by the defendant, was held to be labeling which accompanied the drug.

Sections 201 (g), 201 (m), 301 (a), 302 (a), Federal Food, Drug, and Cosmetic Act.

It was the purpose of Congress to treat advertising matter as labeling if used by the purchaser in the same way as if the matter were accompanying the drug in the first place.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.



Objection was properly made to testimony by defendant that the years of his treatment by mail had not been attended by complaints from patients.

It is the majority rule that medical books are not competent as evidence.

Although the defendant had died since the trial and submission of the case, inasmuch as the Government was entitled, at the time the case was tried, to a decree as prayed, a decree would be entered *nunc pro tunc* as of the date of the submission of the case.

Sections 301 (a), 302 (a), Federal Food, Drug, and Cosmetic Act.

David A. Thompson, U. S. Attorney, for plaintiff.

Charles Rowan, Milwaukee, Wis., for defendant.

#### Memorandum Opinion on Merits of Case

REEVES, District Judge: This is an action under Section 332 (a) Title 21 U. S. C. A. to restrain the defendant from violations of Section 331 of said Title 21 U. S. C. A., in the following particular: The introduction of certain alleged misbranded drugs into interstate commerce. The issues were made up by an answer of the defendant which denied "that he is transporting misbranded drugs in interstate commerce \* \* \*."

#### [Plaintiff's Evidence]

The evidence on the part of the plaintiff tended to show that the defendant has been continuously from 1932 until the present time engaged in the business of distributing through the mails in interstate commerce drugs to be used in the treatment of gall stones, gall bladder diseases and diseased liver conditions, and that said drugs consisted of yellow coated tablets, blue coated tablets and brown coated tablets, and that such drugs were within the meaning of Section 321 (g) (2), Title 21 U. S. C. A. The evidence supported the averments of the complaint that certain exhibits proffered in the complaint and in evidence were regularly sent through the mails either with the drug thus distributed or prior or subsequent to its distribution and that the drugs and the literature came into the hands of patrons or purchasers of the drug and that such literature was intended by the defendant to be used in connection with the treatment advised by the defendant. As an illustration of the literature thus distributed through the mails to be associated with the drug when used, was one as follows:

(Exhibit H)

"HEARTFELT GRATITUDE  
from NORTH . . . SOUTH . . . EAST  
and WEST"

(Printed in large type)

and this was followed by a statement, blocked off in the advertisement (also in large type) as follows:

"Does Gall Bladder Irritation, Gall Distress and Sluggish Bile Threaten You? Then read

MY 30 YEARS OF TREATING  
Earlier Symptoms to Avoid  
Development of  
GALLSTONE  
TROUBLES."

The two words GALLSTONE TROUBLES were printed in very large type.

#### [Testimony of Physicians]

Four physicians who were specialists in the administration of internal medicines, and particularly familiar with gall bladder and liver complaints, testified that the drugs distributed by the defendant were ineffective for the purposes advertised and asserted by the defendant in his literature. And, moreover, that said drugs would be ineffective in the prevention or the avoidance of the development of gallstone trouble. In fact, the testimony of these experienced physicians indicated that the drugs administered or delivered for administration by the defendant would act in a degree as an irritant and would be harmful in their use. Moreover, said witnesses further testified that diagnosis of gall bladder and liver trouble could not be satisfactorily made without a preliminary objective and subjective examination of the patient.

On the part of the defendant two physicians were called who were not presently engaged in the practice of medicine and who had had little experience in the treatment of gall bladder and liver complaints. The witnesses for the defendant tended to support the contention of the defendant that his drugs were not misbranded and that they were useful and efficient as stated by him in his literature. The further contention is made by counsel for the defendant that the literature transmitted through the mails in interstate commerce was in no sense a labeling of the drugs but was purely advertising matter.



[Labeling Defined]

1. The word "labeling" has been defined in the Federal Food, Drug, and Cosmetic Act, (New) Section 321, paragraph (m), Title 21 U. S. C. A. as follows:

"(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

As said by the Court of Appeals, 7th Circuit, in *United States v. Lee*, 131 F. 2d 464, 1. c. 466:

"The word 'accompany' is not defined in the Act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with' \* \* \*. There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. *It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.*"

Other discussions of the subject would indicate that it was the purpose of Congress to treat advertising matter as labeling, if used by the patron or purchaser, precisely in the same way as if the matter were accompanying the drug in the first instance.

[Defendant's Formula Harmful]

2. There is the further contention by the defendant that the testimony on behalf of the government did not point out that the particular formulas of the defendant were harmful. In the first place, in the trial of the case, it was assumed by all of the witnesses, both for the plaintiff and the defendant, on direct examinations and cross-examinations, that the precise formulas were in controversy and were under discussion by the expert witnesses, and, in the second place, the testimony on behalf of the government was that, without regard to precise formulas, the particular constituents of the formula or formulas were harmful and dangerous unless prescribed after a careful diagnosis of the patient's troubles.

[Testimony by Defendant]

3. The defendant testified over the objec-

tion of counsel for the government that the years of his treatment by mail had not been attended by complaints from patients or patrons. Objection was properly made to such testimony and same should have been excluded. Moreover, certain medical books or texts were offered in evidence by the defendant over the objections of the plaintiff. It is the rule in this circuit, as in practically all of the states, that medical books are not competent as evidence.

[Literature Held Labeling]

The overwhelming preponderance of the testimony was that the labeling and the literature treated as labels on the drugs introduced by the defendant into interstate commerce constituted a misbranding of drugs and that the government was entitled to have the defendant restrained from the further introduction of said drugs in interstate commerce.

The attention of the court has been called to the fact that since the case was tried and submitted the defendant has deceased. The government, therefore, could proceed no further in the case. Since the government was entitled, at the time the case was tried, to a judgment or decree as prayed, and, in view of the death of the defendant, a decree will be entered *nunc pro tunc* as of the date the case was submitted.

Findings of Fact

I make the following FINDINGS OF FACT:

1. All of the literature used by the defendant and offered in evidence, whether used over the container of the drug or in the packages, actually physically accompanying the drug, or whether sent before, or subsequently, served the function of labeling and should be treated as such.

2. Such literature and drugs were introduced and were being introduced by the defendant in interstate commerce through the mails as alleged in the complaint.

3. Said literature was intended by the defendant as a labeling of his drug and actually served that purpose as well as for advertising matter.

4. Said literature as labeling matter misrepresented the efficaciousness of said drug or drugs and operated as a fraud upon the public.

Conclusions of Law

I state the following CONCLUSIONS OF LAW:



1. The defendant having misbranded his drugs by labels attached thereto or accompanying same, and such misbranding having been done in interstate commerce, the defendant should be enjoined from further violations of Section 331, Title 21 U. S. C. A.

## UNITED STATES v. DEAN RUBBER MFG. CO. ET AL.

United States District Court for the Western District of Missouri, Western  
 Division. No. 638. October 7, 1946. 71 F. Supp. 96.  
 Later opinion, 72 F. Supp. 819. See page 471.

An information was filed alleging that a permanent injunction had been entered restraining the defendants from introducing defective prophylactics in interstate commerce, and that the assets of the corporation had been transferred to certain individuals who had violated the injunction with knowledge of its contents. Under Rule 65 (d) of the Federal Rules of Civil Procedure, mere knowledge, in and of itself, of the issuance of an injunction, would not make a person not a party to the injunction suit liable in contempt for committing an independent act not done "in active concert or participation with" a party bound by the injunction.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

If the corporation which transferred its assets retained its legal entity, the information should be amended to set forth such fact.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

It is doubtful that an assignment of assets alone is sufficient to make the assignee bound by an injunction decree.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

It is only injunctions acting *in rem* that bind successive ownerships of the *rem*.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

The Government was given leave to amend its information so as to state the facts concerning the privity existing between the corporation which transferred its assets and the individual contemnors.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

Sam M. Wear, U. S. Attorney, and Harry F. Murphy, Assistant U. S. Attorney, for plaintiff, the United States.

Stinson, Mag, Thomson, McEvers & Fizzell, of Kansas City, Mo., for defendants.

### Memorandum Opinion

[*Permanent Injunction Entered Against Defendants*]

RIDGE, District Judge: The amended information filed herein alleges that on September 11, 1940, a permanent injunction was entered against the Dean Rubber Company, a Corporation, by which said defendant, its officers and agents and all persons then or thereafter acting by, through or under it or them, were perpetually enjoined and restrained from distributing, in interstate commerce, "any of the stock of defective rubber prophylactics which it had on hand at Kansas City, Missouri, or at any other point, or any other quantity of defec-

tive rubber prophylactics it might subsequently acquire."

[*Transfer of Assets*]

In Paragraph 2 of the information it is alleged that W. J. Dean was the President and Acting Manager of said Dean Rubber Company, a Corporation; that on or about the 21st day of October, 1944, the assets and business of said Corporation were transferred to certain individuals who, since that time, have been and are now operating as co-partners under the style and trade name of Dean Rubber Company; that at the time of such transfer "each of the within-named individual defendants had



actual knowledge of the contents of said injunction order."

[*Violation of Injunction Decree Alleged*]

Rule 65 (d) F. R. C. P. provides that an order granting an injunction "is binding only upon the parties to the action, and officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise." Under said rule mere knowledge, in and of itself, of the issuance of an injunction would not make a person, not a party to an injunction suit, liable to contempt proceedings for committing an independent act not done in "active concert or participation with" a party bound by the injunction. *Alemite Mfg. Co. v. Staff*, 42 F. (2d) 832; *Harvey v. Bettis*, 35 F. (2d) 349. The amended information does not allege how or in what manner the alleged individual contemnors, named therein, acted in concert or participation with the corporate defendants in violating the injunctive decree. All that is alleged in the 3rd and subsequent paragraphs of the information is that "said defendants did wilfully, unlawfully, contumaciously and contemptuously ship and cause to be shipped in interstate commerce" certain defective rubber prophylactics. There was only one defendant in the original action, namely, the Dean Rubber Manufacturing Company, a corporation. If the individuals named in the amended information are guilty of violating the injunction decree of this Court, then they are "contemnors" and not defendants, and the information must allege a "privity" between defendant and said individuals.

In its suggestions in opposition to the motion to dismiss the Government states "the corporation, for some reason, did transfer its assets but, at the same time retained its legal entity and continued in active operation of its business." If such be a fact, then the amended information should be amended and the facts set out concerning such matters. As the information now stands no such issue is presented. All that is alleged, in the instant information, is a succession to the assets of the business of the corporation by the individuals named as alleged contemnors therein. It is doubtful whether an assignment alone is sufficient to make the assignee

bound by an injunction decree. The facts showing the privity between the original parties to the suit and the assignee, or stranger to the action should be alleged so that the information, upon its face, shows a mutual or successive relationship of such parties to the subject matter of the injunction decree.

[*Nature of Injunction Decree*]

It is noted that the injunction decree in part is *in personam* and in part *in rem*, i.e., the injunction decree enjoins the corporation from distributing, in interstate commerce, "any of the stock of defective rubber prophylactics which it now has on hand." That portion of said decree is *in rem*. The prohibition of the decree which enjoins distributing in interstate commerce, "any other quantity of defective rubber prophylactics which it may subsequently acquire," is *in personam*. It is only injunctions, acting *in rem*, that bind successive ownerships of the *rem*. *Alemite Mfg. Co. v. Staff*, *supra*; *Rivera v. Lawton*, 35 F. (2d) 823. 28 Am. Jur. p. 505, etc. Only persons who are parties to an injunction decree, or in privity with those whose rights have been adjudicated thereby, are bound by a *personam* decree. *Chase Nat'l. Bank v. Norwalk*, 291 U. S. 431.

[*Plaintiff To File Amended Information or Dismissal Motion To Be Sustained*]

In view of the statement contained in plaintiff's suggestions that "the evidence on behalf of the plaintiff will disclose that the individual defendants were employees or officers of the corporation at the time judgment was entered against it" and it appears that plaintiff contends that the individual contemnors are "acting by, through or under" Dean Rubber Manufacturing Company, or that perhaps said individuals were the sole owners of the stock of said corporation at the time the injunction was granted, plaintiff will be given leave to amend its amended information so as to state the facts concerning the privity existing between said corporation and the individual contemnors. If plaintiff does not file an amended information within ten days, defendant's motion to dismiss will be sustained.

It is so ordered.



## HYGRADE FOOD PRODUCTS CORPORATION v. UNITED STATES

United States Circuit Court of Appeals for the Eighth Circuit. No. 13,386.  
April 9, 1947. 160 F. 2d 816.

A judgment was entered in the District Court enjoining the defendant from shipping in interstate commerce any of its products. It was held, on appeal, that the jurisdiction of the court was limited to restraining violations of Section 301 (a); to wit, the introduction into interstate commerce of products that are adulterated or misbranded.

Sections 301 (a), 302 (a), Federal Food, Drug, and Cosmetic Act.

An injunction is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed. The denial, in the injunction decree, of the right to apply to the court for a modification of the decree within a period of two years was contrary to the genius of the jurisprudence of chancery.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.

The injunction was too broad in that it restrained the defendant from shipping any products, and the decree should be modified so as to restrain the defendant from introducing into interstate commerce adulterated products and so as to contain a recital that jurisdiction was retained for the purpose of enforcing or modifying the decree.

Sections 301 (a), 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

An injunction should forbid only the acts which are prohibited by the statute; it should not prohibit the shipping or introducing of pure products into interstate commerce.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.

George C. Claassen and Paul J. Donovan, for appellant.

Tobias E. Diamond, U. S. Attorney (William B. Danforth, Assistant U. S. Attorney, with him on the brief), for appellee.

Before GARDNER, THOMAS and RIDDICK, Circuit Judges.

GARDNER, Circuit Judge, delivered the opinion of the Court:

### *[Appeal Against Injunction Decree]*

This is an appeal from a judgment entered in an action brought by the Government against Hygrade Food Products Corporation under the provisions of the Federal Food, Drug, and Cosmetic Act, which enjoined appellant from shipping in interstate commerce any of its products processed and manufactured at its Manchester, Iowa, plant. It will be convenient to refer to the parties as they appeared in the trial court.

### *[Shipment of Adulterated Products by the Defendant]*

The defendant, since March, 1944, has owned and operated a plant at Manchester, Iowa, and has been engaged in the processing of cheese and cheese products from

milk, and shipping these products in interstate commerce. It is charged in the complaint that these products have become contaminated with filth, rendering them injurious to health, and were adulterated in violation of Section 342 (a), (3) and (4), Title 21, U. S. C. A. After hearing the court found that defendant acquired its plant at Manchester, Iowa, in March, 1944, and has since been engaged in the processing of cheese and cheese products from milk, and has been shipping and introducing the products so processed into interstate commerce; that under the standards used by the Administrator of the Federal Food, Drug, and Cosmetic Act, milk as to sediment content is classified into five grades known as Grades 1 to 5 inclusive; that Grade 1 is milk which is practically free from sediment; that Grade 2 is milk in which there is only a very small amount of sediment; that Grade 3 is milk in which



there is a moderate amount of sediment; that Grade 4 is milk in which there is a large amount of sediment, and that Grade 5 is milk in which there is a very large amount of sediment; that milk which grades 1 and 2 is highly fit and satisfactory for processing into cheese; that milk which grades 3, while undesirable, does not have such a heavy sediment content as to result in filthy cheese, but that milk which is graded 4 and 5 is such filthy milk as to result in filthy cheese. The court then sets out the results of various inspections of the defendant's plant at which milk was graded. The court found that the problem of filthy milk in the area of defendant's Manchester, Iowa, plant has been aggravated by war time conditions in that the farmers have been short of help; that the defendant, commencing in July, 1945, for the first time began to cope with the filthy milk situation and has spent some time, effort and expense on the problem; that it made special provisions for an employee to do something about the filthy milk situation by carrying on an educational campaign among the milk producers; that it made arrangements to have tests made of the milk as delivered at the plant and as a result the number of defendant's patrons have been reduced from around one hundred to fifty-eight; that the producers of filthy milk whose product is rejected by defendant frequently thereafter sell their filthy milk or cream to certain of defendant's competitors, but that defendant since it began operating the Manchester plant has been a large outlet for filthy milk and a hindrance to those purchasers of milk and cream who are trying to raise the standards of dairy cleanliness, and that certain of defendant's competitors now operate as a hindrance to the defendant when it is trying to raise the standards of dairy cleanliness; that since July 16, 1945, defendant has put considerable pressure on its patrons to quit delivering filthy milk, but when defendant relaxes this pressure a number of such patrons lapse back into dairy uncleanliness, and that when government pressure is released as to defendant it relaxes back into acceptance and processing of filthy milk. The court found, "That the defendant has shown that it can and will do everything necessary to place its plant at Manchester, Iowa, in proper condition for the production of cheese, and no injunction is needed as to that phase." The court also found that because of competitive conditions and the desire to secure milk the pressure on defendant to accept filthy milk

was such that defendant could not resist it and that before defendant would be able to refrain from using filthy milk a very substantial change in the entire background in the matter of dairy cleanliness in the area served by its plant would have to occur. The court found that unless restrained by the court defendant would ship in interstate commerce dairy products processed at its Manchester, Iowa, plant contaminated by filthy substances contrary to the provisions of Title 21, U. S. C. A., Secs. 331 (a) and 342 (a) (3). The court entered judgment restraining defendant.

[*Injunction Decree*]

"\* \* \* from shipping or introducing into interstate commerce any cheese or other dairy products processed at its Manchester, Iowa, plant.

"It is further ordered that after the expiration of two years, the defendant may move to modify this judgment so as to permit it to ship or introduce into interstate commerce cheese or other dairy products processed at its Manchester, Iowa, plant on the ground that there has been such a change in circumstances as to justify the expectation that such products will be processed without the use of filthy milk."

[*Defendant's Contentions*]

In seeking reversal defendant challenges the court's findings and conclusions on substantially the following grounds: (1) the court should have refused an injunction because defendant is a responsible and reputable party and no present intention to violate the law appears; (2) the injunction should not be entered against the defendant as a penalty for past infractions; (3) injunctive relief provided for under Section 332, Title 21 U. S. C. A., presupposes a temporary injunction only with opportunity to the defendant to show a change of circumstances; (4) under Section 332, Title 21 U. S. C. A., the court was without authority to enjoin a processor or shipper from shipping its unadulterated products in interstate commerce.

Section 331, Title 21 U. S. C. A. prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and Section 332 of the same title confers jurisdiction upon the District Courts of the United States "for cause shown \* \* \* to restrain violations of Section 331."



*[Injunction Is Arbitrary]*

When defendant acquired the Manchester plant in March, 1944, it was in a dilapidated and unsanitary condition so far as the equipment and buildings were concerned and the manager was apparently careless and incompetent. Since that time defendant has discharged the old manager who had been in the employ of defendant's predecessor and employed a skilled and competent manager to take his place. It has made very substantial repairs, additions, improvements and changes in its physical structures so that the court found, "That the defendant has shown that it can and will do everything necessary to place its plant at Manchester, Iowa, in proper condition for the production of cheese, and no injunction is needed as to that phase." The basis for granting the injunction lies in the fact that defendant's supply of milk was up to the time of the hearing below the standard required although the defendant had with apparent good faith been endeavouring to educate the producers to furnish a better grade and in so doing had rejected unfit milk to such an extent that it had lost about forty per cent of its patrons. The importance of these recitals goes simply to the question of the defendant's good faith. As above noted, it has replaced its incompetent plant manager with a competent and skilled one and at a large expenditure has so improved the condition of its plant that no injunction is needed so far as the sanitary condition of the plant is concerned, nor indeed, so far as the present personnel of the management is concerned. The fact remains, however, that the milk supply which was being received at the plant even up to the time of hearing was not up to the required standard and this warranted the court in granting an injunction. The jurisdiction of the court, however, is limited to restraining violation of Section 331, and that is the introduction or delivery for introduction into interstate commerce of products that are adulterated or misbranded. An injunction is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed. *White v. Sparkill Realty Corp.*, 280 U. S. 500; *Duplex Printing Press Co. v. Deering*, 254 U. S. 443; *Bowles, Adm. v. Carnegie-Illinois Steel Corp.*, 7 Cir., 149 F. 2d 545. The injunction here absolutely closes the door of the court on the defendant for an arbitrary period of two years regardless of what changes may be brought about dur-

ing that time. Defendant can not even ask the court to modify the injunction. This is true for a period of two years even though the grounds for which it was granted no longer exist by reason of a change in the controlling facts on which the injunction rested. The injunctive decree should be an ambulatory one. It is executory and continuing as to its purpose and should be subject to adaptation as events may change. This is not a case in which rights may be said fully to have accrued upon facts which are stable, permanent and impervious to change, but it involves the supervision of changing conduct or conditions. The denial of the right to apply to the court for a modification of the judgment within a period of two years is contrary to the genius of the jurisprudence of chancery. Under our system of government even the social outcast or the convicted criminal, though shunned by society, may have his day in court and seek for justice. We think too, the injunction is too broad in that it restrains the defendant from shipping any products processed at its Manchester plant regardless of what the grade of the processed products might be. As has been observed, the physical plant itself is in sanitary condition; it is competently managed. It has not apparently been able to secure raw material of the requisite grade. It is surely conceivable that with its present equipment and personnel, defendant could process products that are not, within the meaning of the statute, adulterated, and if so, it should be permitted to have such products transported in interstate commerce.

*[Injunction Modified]*

The judgment appealed from should be modified so as to enjoin and restrain defendant, under the provisions of Section 332, Title 21 U. S. C. A., from introducing or delivering for introduction into interstate commerce, in violation of Section 331 and Section 342 (a) (3), Title 21 U. S. C. A., adulterated cheese or dairy products processed or manufactured, or to be processed or manufactured at its Manchester, Iowa, plant. The judgment should contain recital that jurisdiction of the cause is retained for the purpose of enforcing or modifying the judgment and for the purpose of granting such further relief as may hereafter appear appropriate. When so modified, the injunction can, of course, be enforced by contempt proceedings if necessary. The injunction should forbid only the acts which



are prohibited by the statute. It should not prohibit the shipping or introducing of pure

products into interstate commerce. As so modified the judgment will be affirmed.

**UNITED STATES v. DEAN RUBBER MFG. CO.,  
A CORPORATION ET AL.**

United States District Court for the Western District of Missouri, Western Division. No. 638. August 1, 1947. 72 F. Supp. 819.

Earlier opinion, 71 F. Supp. 96. See page 466.

Contempt proceedings were instituted by the Government charging violation of an injunction prohibiting the distribution in interstate commerce of defective merchandise. The Clayton Act governs the procedure in criminal contempts which consist of "criminal offenses" under any statute of the United States, except insofar as certain contempts are expressly excluded from its terms; the Clayton Act is neither a grant nor limitation on the powers of the federal courts to punish for contempts, but only prescribes and limits the procedure as to punishment for contempts within the purview thereof.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

Section 302 (b) of the Federal Food, Drug, and Cosmetic Act did not place criminal contempt proceedings for violations of injunctions within the purview of all the provisions of the Clayton Act; it incorporated into the former statute the section in the latter statute which sets up a procedure to be followed in the trial and punishment of contempts for violation of injunctions.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

Section 24 of the Clayton Act, establishing a one-year limitation of action, is not specifically made to apply, and does not apply, to contempt proceedings instituted for violations of injunctions obtained under the Federal Food, Drug, and Cosmetic Act; such proceedings are subject to the general three-year statute of limitations.

Sections 302 (a), 302 (b), Federal Food, Drug, and Cosmetic Act.

Sam M. Wear, U. S. Attorney, for plaintiff.

Stinson, Mag, McEvers, Fizzell & Rhodes, Kansas City, Mo., for defendant.

RIDGE, Albert A., District Judge: Contemnors herein have moved to dismiss the "Third Amended Information" on the ground that the several alleged criminal violations of the injunctive decree charged therein, having occurred more than one year before the filing of said information, are barred by limitations provided in 28 U. S. C. A. 390 (Section 25 of the Clayton Act).

*[Injunction Decree]*

The final injunction decree upon which said information is premised was entered on September 11, 1940, in an action instituted by the United States for that purpose, perpetually enjoining and restraining the Dean Rubber Manufacturing Company, a corporation, its officers and agents, and persons then or thereafter acting by,

through or under it, or them, from distributing in interstate commerce any of the stock of defective rubber prophylactics which it then had on hand at North Kansas City, Missouri, or at any other point, or any other quantity of defective rubber prophylactics which it might subsequently acquire, "defective," within the meaning of the order; except in compliance with Section 381 (d), U. S. C. A., Title 21 (The Federal Food, Drug, and Cosmetic Act) (52 Stat. 1041, etc.).

*[Section 302 (b) of the Food, Drug, and Cosmetic Act]*

Section 302 (b) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1043; Title 21, Section 332 (b), U. S. C. A.), provides that "in case of violation of an in-



junction . . . issued under (the act), which also constitutes a violation of (the act) . . .” the trial for such violation may be before the Court, or a jury if requested, and “shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of Section 387 of Title 28, as amended.”

[*The Clayton Act*]

Section 387 of Title 28 is Section 22 of the Clayton Act. The Clayton Act governs the procedure in criminal contempts which consist of “criminal offenses” under any statute of the United States or of any State, except insofar as certain contempts are expressly excluded from its terms. The Clayton Act is neither a grant nor a limitation on the powers of the Federal Courts to punish for contempts, but only prescribes and limits the procedure as to punishment for contempts within the purview thereof. After enumerating the contempts as to which the procedure of the Clayton Act is to be followed, Section 24 of said Act (Title 28, Section 391, U. S. C. A.) expressly excludes from its operations, (1) contempts committed in, or near to, the presence of the Court as to obstruct the administration of justice, and (2) “contempts committed in disobedience of any lawful writ, process, order, rule, decree, or command entered in any suit or action brought or prosecuted in the name of, or on behalf of, the United States.” As to the latter excluded criminal contempts from the provisions of the Clayton Act, it is held that they fall under the general three-year statute of limitation (Title 18, Section 582, U. S. C. A.) *U. S. v. Goldman*, 277 U. S. 229; *Hill v. U. S. ex rel. Weiner*, 300 U. S. 105; and that as provided in Section 24 of said Act (Title 28, Section 389, U. S. C. A.), punishment therefor may be assessed “in conformity to the usages at law and in equity prevailing on October 15, 1914.” If the instant action was prosecuted by the United States under the Anti-Trust Act, or similar Act of Congress, there could be no doubt but that the alleged criminal contempts here sought to be prosecuted would not be barred by the one-year period of limitation provided in Section 25 of the Clayton Act (Title 28, U. S. C. A., 390). *U. S. v. Goldman* and *Hill v. U. S. supra*.

[*Contemnors' Contention*]

Contemnors maintain, however, that Section 302 (b) of the Federal Food, Drug, and Cosmetic Act, *supra*, by expressly subjecting

proceedings for violations of injunctions under that Act to the same rules as proceedings under Section 22 of the Clayton Act, *supra*, made an “exception to the exception” contained in the Clayton Act as to criminal contempts prosecuted by the United States, because all proceedings instituted for the enforcement, or to restrain violations of the Federal Food, Drug, and Cosmetic Act, are brought in the name of the United States. (21 U. S. C. A. 337.) They say, “What a futile thing would Congress have done if . . . all injunction violations under the Food and Drug Act are governed the same as proceedings under Section 387, but since Section 389 (Title 28, U. S. C. A., Sections 387, 389) exempts all such proceedings Congress merely put such proceedings within the Clayton Act and by the same words took them out from under the Clayton Act.”

[*Section 302 (b) Establishes Limited Special Procedure*]

Section 302 (b) of the Federal Food, Drug, and Cosmetic Act (Title 21, U. S. C. A., 332 (b)) did not place criminal contempt proceedings for violations of injunctions procured by the United States, under the Food and Drug Act within the purview of all the provisions of the Clayton Act. All that is accomplished by the provisions of Section 302 (b), *supra*, is to incorporate into the Federal Food, Drug, and Cosmetic Act one section of the Clayton Act (Section 22), which section sets up a procedure to be followed in the trial and punishment of contempts for violations of an injunction procured under the Federal Food, Drug, and Cosmetic Act. Notice the language used in Section 302 (b), *supra*, is that “trials” for contempt in case of violation of an injunction procured under the Federal Food, Drug, and Cosmetic Act are to “be conducted in accordance with the practice and procedure applicable in the case of *proceedings subject to the provisions of* Section 387 of Title 28, as amended.” The only “proceedings” that are “subject to the provisions of Section 387,” *supra*, are criminal contempt proceedings arising in litigations where the “order . . . decree or command entered is *not* in a suit or action brought or prosecuted in the name of, or on behalf of, the United States.” In other words, in litigation of a private nature, and such criminal contempts as are committed and prosecuted under miscellaneous Federal statutes authorizing punishment for contempt without desig-



nating the particular contempt as civil or criminal and generally containing no provisions as to procedure, as in the Federal Rules of Civil Procedure. (See Rules 37 (b) (1); 45 (f); 56 (g) and 70.) In providing that Section 22 of the Clayton Act shall be the procedure to be followed in prosecution of alleged contempts for violation of injunctions procured under the Federal Food, Drug, and Cosmetic Act, Congress established a limited special procedure to be followed in such cases and took such contempt actions out of the procedure generally followed "at law and in equity" in cases wherein the United States was the party procuring an injunction, decree or order. Without such limitation contained in Section 302 (b) of the Federal Food, Drug, and Cosmetic Act, the alleged contumacious conduct here charged against contemnors would be prosecuted under Section 268 of the Judicial Code (Title 28, U. S. C. A. 385). In changing the procedure previously established as to criminal contempts prosecuted in the name of the United States so far as such contempts may arise under the Federal Food, Drug, and Cosmetic Act, Congress did not provide that other sections of the Clayton Act (other than Section 22 thereof) be made applicable to contempt proceedings arising under the Federal Food, Drug, and Cosmetic Act, as asserted by contemnors. To sustain such contention would work the anomalous situation which contemnors state, namely, that Congress "put such proceedings within the Clayton Act and by the same words took them out from the Clayton Act." Section 24 of the Clayton Act (Title

28, U. S. C. A. 389) would produce such a paradoxical result. Under contemnors' position, all the sections of the Clayton Act relating to contempt proceedings must be presumed to have been intended by Congress to apply to criminal contempt proceedings instituted under the Federal Food, Drug, and Cosmetic Act, and not only Sections 22 and 25 thereof, (Title 28, U. S. C. A. 390.) To make such assumption is to charge Congress with being a paradoxer. Congress cannot be so charged with such self-annulling action as asserted by contemnors.

*[Limitation Effective Only If Made So Specifically]*

Section 24 of the Clayton Act, *supra*, is not specifically made to apply to contempt proceedings instituted under the Federal Food, Drug, and Cosmetic Act, as is Section 22 of said Act. Section 24 of the Clayton Act establishes a limitation of action. A statute creating a limitation against the bringing of an action is never assumed to be effective as against actions instituted by the Federal Government and is only effective against such actions when specifically made so. Exemption from statutes of limitation ordinarily is implied in favor of the State and Federal Government. (34 Am. Jur. 303, etc.)

From what has been heretofore said, it is not necessary to discuss other points raised by contemnors in their briefs.

**Order**

Contemnors' motion to dismiss this action is by the Court overruled.

---

**UNITED STATES v. COWLEY PHARMACEUTICALS, INC.**

United States District Court for the District of Massachusetts. Civil  
No. 7369. March 30, 1948.

The purpose of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public.

Title, Federal Food, Drug, and Cosmetic Act.

The Act is sufficiently broad to allow the issuance of an injunction even though no wilfulness or knowledge on the part of the respondent or its agents is shown.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.

A preliminary injunction should not issue unless the Government makes out a case where there is a strong probability that the respondent's allegedly illegal acts will continue in the future.

Section 302 (a), Federal Food, Drug, and Cosmetic Act.



Federal Food, Drug, and Cosmetic Act  
*U. S. v. Cowley Pharmaceuticals, Inc.*

HEALEY, District Judge: This matter came on for hearing on a return order of notice requiring the respondent to show cause why a preliminary injunction as prayed for in the complaint should not issue against the respondent, its officers, agents, servants, employees and attorneys and all other persons in active concert or participation with them.

This court has jurisdiction of this matter under Section 302 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 332 (a)).

#### Findings of Fact

1. The respondent, Cowley Pharmaceuticals, Inc., is a Massachusetts Corporation having its principal place of business in Worcester, Massachusetts.

2. The respondent is and has been engaged in the manufacture and sale of various articles of drug and articles of food, a large quantity of which are sold and shipped in interstate commerce.

The government has submitted evidence that on various dates during the period from June 4, 1946 to November 2, 1947, the respondent, in violation of 21 U. S. C. A. Sec. 331 (a), shipped in interstate commerce certain articles of drug as defined by 21 U. S. C. A. 321 (g) (1), (2), and (3), and certain articles of food as defined by 21 U. S. C. A. Sec. (f) (1) which were allegedly adulterated and misbranded, in the particulars stated in Exhibit A appended to the complaint.

4. In all cases but one, the product is allegedly adulterated and misbranded because it allegedly contained a different quantity of some constituent part than was stated on the label. In the case of the soda mint tablets, it is alleged that they contained aspirin, the presence of which was not disclosed on the label.

5. There is no evidence that any inspection of respondent's factory has been made by any agent of the Food and Drug Administration since October 1, 1947.

6. There is no evidence that any adulterated or misbranded articles of drug or food have been shipped in interstate com-

merce by the respondent since the shipment made on November 2, 1947.

7. By his affidavits, Benjamin C. Cowley, president and treasurer of the respondent, states that he has adopted the recommendations made by the government agents and inspectors regarding improvements in respondent's factory, facilities and methods of manufacture so as to eliminate the probability of any future violations of the Act.

#### Discussion

The purpose of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public, *United States v. Lord-Mott Company*, 57 F. Supp. 128; *United States v. Crown Rubber Sundries Company*, 67 F. Supp. 92; *Federal Security Administrator v. Quaker Oats Company*, 318 U. S. 218, and the Act is sufficiently broad to allow the issuance of an injunction even though no wilfulness or knowledge on the part of the respondent or its agents is shown. *United States v. Greenbaum*, 138 F. (2d) 437.

However, in my opinion, a preliminary injunction should not issue unless the government makes out a case where there is a strong probability that the respondent's allegedly illegal acts will continue in the future.

In the instant case, the complaint was filed on February 26, 1948, more than three months after the last alleged violation of the Act, and almost five months after the last inspection of respondent's premises by the government agents. In the light of the affidavits presented by the respondent containing statements that the causes for any possible violations have been eliminated, and in the absence of any evidence of recent violations, there is not sufficient evidence of the probability of any future violations to warrant the issuance of a preliminary injunction as prayed for.

#### Conclusion of Law

1. The complainant has not produced sufficient evidence of the probability of future violations of the Act by the respondent to warrant the issuance of a preliminary injunction.



UNITED STATES v. RUNKLE COMPANY, ET AL.

United States District Court for the Northern District of Ohio.  
No. 5431 Civil. December 29, 1948.

Defendants moved for an order vacating a decree of injunction entered under the Act. They represented that the Food and Drug Administration had been requested to make another inspection of their plant and to report to the court. The report of the Administration stated that considerable improvement had been made in the sanitary condition of the plant, but that many other improvements should be made; it also recommended against vacating the decree. The court declared that, in view of such report and recommendation, the defendants' motion would be overruled, and that if a satisfactory report following an inspection were made by the Food and Drug Administration, the court would then be in a position to entertain a motion to set aside the decree of injunction.

Sections 302 (a), 402 (a), Federal Food, Drug, and Cosmetic Act.

**Memorandum on Motion To Set Aside  
the Injunction**

KLOEB, District Judge: On October 5, 1948, the defendants moved the court for an order to vacate and set aside the injunction heretofore issued on December 30, 1946.

In the memorandum attached to the motion, the defendants represented that they had requested the Food and Drug Administration to make another inspection of the plant and report to the Court the conditions found at the time of such inspection, and that this request had been made through the office of the District Attorney.

Under date of October 26, 1948, the Food and Drug Administration, through its Cincinnati office, wrote the District Attorney a summary of an inspection that had been made on October 21, 1948, and attached thereto a copy of the report of the inspection. In this report, under the heading *Recommendations Made To Manufacturer*, we find the following:

"Following the inspection the conditions noted above were discussed with Mr. Johnson and Mr. Stoffel. They said that immediate steps would be taken to eliminate the mice from the building. Mr. Johnson also said that he was going to have the peanut blancher removed from the building since the limited use of the equipment did not compensate for the danger of insect infestation due to its presence.

"They were also cautioned regarding the improper protection of scrap candy that is held in open trays and exposed to possible contamination from rodents. Certain other practices of the employees that were observed such as standing covers of the fondant tubs on the floor and use of dirty cloths for wiping hands were also

called to their attention.

"They were advised that considerable improvement had been made in the factory conditions but that many other improvements should also be made before the factory would be considered entirely satisfactory. Removal of all unused equipment and rearrangement of the operations in the bakery section would materially improve the housekeeping conditions. Mr. Johnson said that they would continue to make these corrections and hoped that in another six months they would have everything in satisfactory condition."

On page one of the letter of October 26, 1948, to the District Attorney, we find the following statements:

"Since Mr. Stoffel has been with the firm only since May 1, 1948, he has not had sufficient time to make all of the necessary changes in their operations and we believe that some additional time is required before we will be in a position to decide whether this factory will continue to be operated in compliance with the terms of the injunction.

"Mr. Walter Johnson, a partner in the firm, was present when the inspection was made on October 21, 1948 and the conditions noted in our report were discussed with him and Mr. Stoffel. Mr. Johnson was told that they had made significant improvement but that because of the conditions noted we would not be in a position to agree that the injunction should be dismissed at this time. Mr. Johnson did not make any objection to this conclusion but stated that they would try to eliminate all of the objectionable conditions as rapidly as possible."

In view of the report of inspection of October 21, 1948, and the report and recommendation of the Food and Drug Administration, contained in their letter to the District Attorney on October 26, 1948, the



Court is of the opinion that the motion for an order vacating and setting aside the injunction ought to be and is overruled.

If and when a satisfactory report follow-

ing an inspection is rendered by the Food and Drug Administration, the Court will then be in position to entertain a motion to set aside the injunction.

---



## MISCELLANEOUS CASES

### HELCO PRODUCTS COMPANY, INC. v. McNUTT, FEDERAL SECURITY ADMINISTRATOR, AND FRANCIS BIDDLE, ATTORNEY GENERAL

United States Court of Appeals for the District of Columbia. No. 8344.  
June 28, 1943. 137 F. 2d 681.

A suit was instituted against the Federal Security Administrator and the Attorney General for a declaratory judgment as to whether white poppy seeds, dyed blue and shipped in interstate commerce, would violate the Federal Food, Drug, and Cosmetic Act. It was held that there was involved no more than an advisory opinion by the Commissioner of Food and Drugs that the shipment of the product in interstate commerce would violate the Act, and that no justiciable controversy existed.

Sections 301 (a), 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Neither the Commissioner of Food and Drugs, nor the Federal Security Administrator, has power to prosecute or to require prosecution under the statute.

Sections 301 (a), 305, 307, Federal Food, Drug, and Cosmetic Act.

The judgment of the Attorney General as to whether the Act has been violated is not in any way controlled by a report from the Federal Security Administrator, or by the declaration or recommendation of an officer subordinate to the Administrator.

Sections 301 (a), 307, Federal Food, Drug, and Cosmetic Act.

The case was not an appropriate one for a declaratory judgment, and there was no showing of an abuse of discretion in the action of the district court in dismissing the complaint.

Sections 301 (a), 402 (b), Federal Food, Drug, and Cosmetic Act.

Louis Halle, with whom Harry P. Warner and Philip J. Hennessey, Jr., were on the brief; David E. Tolman; for appellant.

Edward B. Williams (of Arkansas Bar), with whom Edward M. Curran, U. S. Attorney, Charles B. Murray, Assistant U. S. Attorney, and Jack B. Tate, General Counsel, Federal Security Agency, were on the brief; Bernard J. Long, Assistant U. S. Attorney, and John P. Burke, Assistant U. S. Attorney; for appellees.

Before PARKER, Circuit Judge, sitting by designation, and MILLER and VINSON, Associate Justices.

#### *[Nature of Suit]*

MILLER, Associate Justice: Appellant sued in the District Court for a declaratory judgment against the Federal Security Administrator and the Attorney General. The case stated in its complaint is, in substance, as follows: Appellant intends to ship in interstate commerce white poppy seeds, for use on bakery products, to which it intends to add a blue color by means of a harmless vegetable dye; the seed would be sold in bulk packages labeled with an explanation of the manner of coloring; the reason for the addition of the color is that blue poppy seeds are more in demand, but, on account

of war-time restrictions of importations, are unavailable; appellant, through its attorney explained its intentions in a letter to the Food and Drug Administration of the Federal Security Agency, and explained why it did not consider its proposed business activities to be at variance with the provisions of the Federal Food, Drug, and Cosmetic Act; it requested an expression of opinion from the Food and Drug Administration as to the legality of the interstate shipment of such a food product, and was advised by Walter G. Campbell, Commissioner of Food and Drugs, that, in the opinion of the Food and Drugs Adminis-



tration, such an artificially colored product would be adulterated within the meaning of Section 402 (b) of the Federal Food, Drug, and Cosmetic Act.<sup>1</sup> Appellant alleged also, in its complaint in the District Court, that on June 3, 1942 it sent to the Attorney General of the United States, the following telegram: "Our client, The Helco Products Company, Inc., 111 Hudson Street, New York, desires to ship white poppy seeds dyed blue with a harmless vegetable dye in interstate commerce. J. K. Kirk of the Food and Drug Administration by radiogram dated December 18, 1941, stated that such action would be a violation of law. This was supplemented by a letter of February 23 signed by W. G. Campbell, Commissioner of Food and Drugs, reaffirming the department's attitude as stated in the radiogram. We should like to know whether you would hold such action on my client's part a violation of law and if you would institute prosecution on such a holding. Kindly wire answer collect, as the matter is being held in abeyance by the Court pending a motion made in an action by my client against Federal Security Administrator for a declaratory judgment." In reply to this telegram, the Attorney General, on June 2, 1942, informed appellant: "Liturgic white poppy seed dyed blue please be advised that the Attorney General is authorized by law to give opinions only to the President and heads of Executive Departments." Upon the basis of these allegations, appellant alleged further that in the event it ships dyed poppy seeds in interstate commerce, the Food and Drug Administration will advise the Attorney General that the shipment thereof constitutes a violation of the Federal Food, Drug, and Cosmetic Act; that the Attorney General will thereupon "effectuate the recommendation of the Food and Drug Administration," by seizing and condemning such dyed poppy seeds in interstate commerce, or, in the alternative, will bring criminal proceedings against appellant, its agents and employees; that

appellant has no adequate remedy at law; wherefore, appellant demands judgment against the Federal Security Administrator and the Attorney General, declaring that the Federal Food, Drug, and Cosmetic Act does not prohibit the interstate shipment of artificially colored poppy seeds, properly labeled.

[Issue *Whether Actual Controversy*]

The issue which we must decide is whether there is a case of actual controversy within the meaning of the Declaratory Judgment Act;<sup>2</sup> in other words, whether the facts alleged, under all the circumstances, show that there is a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.<sup>3</sup> In *John P. Agnew & Co. v. Hoage*<sup>4</sup> this Court said that "mere supposition that the appellee's opinion will be erroneously and illegally applied," was not sufficient to support a complaint for a declaratory judgment. This is equally true in the present case. Here, no opinion had been expressed by either appellee named in the complaint. The Attorney General declined to answer the hypothetical question submitted to him; and it does not appear that the question was even submitted to the Federal Security Administrator. Appellant concedes that the *Agnew* case, and others,<sup>5</sup> speak in terms of an official threat of enforcement, as a requisite of justiciability in declaratory judgment actions. But appellant would distinguish the present case on the theory that: "In the case at bar the Administrator has the authority and *as a matter of law has officially threatened* to prosecute the appellant or to seize and libel its merchandise." [Italics supplied.] Specifically, it argues that (1) an oral or written threat of enforcement is not an absolute condition precedent to the use of the declaratory judgment, when (2) the threat of prosecution "is implicit in the statute by reason of the civil and criminal sanctions

<sup>1</sup> In support of this allegation appellant submitted, as an exhibit, a letter from the Commissioner of Food and Drugs which contains the following paragraph: "It is therefore our considered opinion that the interstate shipment of this artificially colored product under any labeling would result in an adulterated product within the meaning of section 402(b) of the Federal Food, Drug, and Cosmetic Act, and that this violation could not be corrected by any form of labeling."

<sup>2</sup> 28 U. S. C. A. § 400.

<sup>3</sup> *Maryland Casualty Co. v. Pacific Coal & Oil*

*Co.*, 312 U. S. 270, 273.

<sup>4</sup> 69 App. D. C. 116, 120, 99 F. (2d) 349, 353.

<sup>5</sup> *Blue Star Auto Stores v. Fleming*, Pike & Fisher, Admin. Law, 72b. 112-1 (D. C. Dist. of Columbia); *Babbitt Auto Parts Co. v. Fleming*, Pike & Fisher, Admin. Law, 72b. 112-2 (D. C. Dist. of Columbia); *F. W. Maurer & Sons Co. v. Andrews* (D. C., E. D. Pa.), 30 F. Supp. 637; *Mushroom Co-operative Canning Co. v. Jacobs* (D. C., E. D. Pa.), 35 F. Supp. 624; *Connecticut Importing Co. v. Perkins* (D. C. Conn.), 35 F. Supp. 414.



attached to the statute"; (3) the declaration, by the Commissioner of Food and Drugs, that the interstate shipment of colored poppy seeds would constitute a violation of the Act, constitutes, as a matter of law, a threat to enforce the statute, and (4) carries with it the duty to report such violation to the Attorney General, who (5) thereupon has the mandatory duty to prosecute a violation of the statute (6) reported to him by the Federal Security Administrator. Several of these propositions, at least, if not all, are without merit; and if appellant's standing to sue depends upon establishing them, then it must fail.

*[Declaration of Commissioner Not Threat of Prosecution]*

Obviously, the declaration of the Commissioner is several steps removed from a threat of prosecution. Neither he nor his superior, the Federal Security Administrator, has power to prosecute or to require prosecution.<sup>6</sup> Moreover, [1] his advisory opinion, in answer to a hypothetical question, does not foreclose a contrary conclusion, by him, upon an actual state of facts; [2] his recommendation for prosecution, assuming that he makes one, does not establish the fact that a violation has occurred; [3] nor does it require the Administrator to recommend prosecution to the Attorney General; [4] while the Attorney General, in the performance of his official duties, has power to decide, or delegate power to decide, whether a particular statute has been violated and, if so, whether to initiate prosecution, his judgment is not in any way controlled by a report from the Federal Security Administrator, much less by the declaration or recommendation of an officer subordinate to the Federal Security Administrator; [5] specifically, he is under no "mandatory duty" to do anything under such circumstances. This is exactly the type of official duty, the performance of which is not subject to control by mandatory process.<sup>7</sup> The language of appellant's contention in this respect is phrased with

interesting disingenuity. It urges its right to a judgment declaring that its proposed business activity will not constitute a violation of the law, while in the same breath it asserts the mandatory duty of the Attorney General to prosecute it for violating the law.

*[Need of Legal Advice Not Sufficient for Declaratory Judgment]*

It does not appear just how far appellant would carry its argument concerning the threat of prosecution which, it says, is implicit in the statute by reason of its civil and criminal sanctions. Here again the argument reduces itself, very quickly, to an absurdity. Certainly such sanctions are convincingly present in laws proscribing homicide and robbery. But, presumably, it would not be seriously contended that one who contemplated killing another, or taking his property, could establish his right to a declaratory judgment, upon a hypothetical case of murder or robbery, by requesting in advance the advice of a grand jury or the attorney general. The fact that one wants<sup>8</sup> or needs legal advice is not sufficient.

*[Declaratory Judgment Not Appropriate]*

We conclude that the present case was not an appropriate one for a declaratory judgment and that there is no showing of abuse of discretion in the action of the District Court dismissing the complaint.<sup>9</sup> The Supreme Court has said the pronouncements, policies, and programs of a government administrative agency do not give rise to a justiciable controversy, save as they have fruition in action of a definite and concrete character, constituting an actual or threatened interference with the rights of persons complaining.<sup>10</sup> To permit suits for declaratory judgments upon mere informal, advisory, administrative opinions might well discourage the practice of giving such opinions, with a net loss of far greater proportions to the average citizen than any possible gain which could accrue.<sup>11</sup> An example of an administrative program, which

<sup>6</sup> 21 U. S. C. A. § 335: "Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.", § 337; 5 U. S. C. A. § 309.

<sup>7</sup> *Hammond v. Hull*, 76 U. S. App. D. C. 301, 131 F. (2d) 23, and cases there cited; *United States ex rel. White v. Coe*, 68 App. D. C. 218,

95 F. (2d) 347, and cases there cited; *United States ex rel. Roughton v. Ickes*, 69 App. D. C. 324, 101 F. (2d) 248.

<sup>8</sup> *F. W. Maurer & Sons Co. v. Andrews*, 30 F. Supp. 637, 638.

<sup>9</sup> *Brillhart v. Excess Insurance Co.*, 316 U. S. 491, 494.

<sup>10</sup> *Ashwander v. T. V. A.*, 297 U. S. 288, 324, 325.

<sup>11</sup> See Borchard, *Declaratory Judgments*, (2d ed. 1941) 919, *et seq.*



was put into action of such definite and concrete character as to create an actual controversy, may be found in *Wallace v. Currin*.<sup>12</sup> The present case constitutes no counterpart of the *Wallace* case. Here, there was no more than an advisory opinion given in response to a hypothetical question.<sup>13</sup> There, the Secretary of Agriculture had virtually taken over the tobacco market of Oxford, North Carolina, by an order effective as of a certain date. The complainants in that case, warehousemen whose business was the selling of tobacco on the Oxford market, were the persons directly affected by the order. Failure to comply with its terms would result in liability for criminal penalties, without more. Here, no order was issued, no steps were taken to put any administrative program into action; appellant was far removed from penalties of any kind. This was not enough.<sup>14</sup>

No doubt, a persuasive argument can be made for extending the use of advisory opinions to all situations in which conflicts may impend, between private business and government agencies, in the working out of policies and programs. Much of the uncertainty of business management could, perhaps, thus be eliminated. What a comfort it would be, if a declaratory judgment could be made as available as an interoffice memorandum, whenever a board of directors meets to consider a proposed new venture. But that millenium has not yet arrived.

*Affirmed.*

Mr. Justice VINSON sat during the argument of this case; concurred in the result when it was considered in conference, but resigned from the Court before the opinion was prepared.

## IN RE UNITED STATES PRAYING FOR A WRIT OF MANDAMUS

United States Circuit Court of Appeals for the Fifth Circuit. No. 10845.  
December 16, 1943. 140 F. 2d 19.

In a seizure proceeding against "ladle butter" and "packing stock butter" alleged to contain filth, the district court entered an order directing the delivery of the butter to claimant at its renovating plant for renovation, jurisdiction being retained to dispose of the butter subsequently. The Government petitioned the circuit court of appeals for a writ of mandamus to compel the district court to vacate the order as being without authority of law. The circuit court of appeals could not, by mandamus, review or set aside the interlocutory order; the circuit court's only function at that time was to decide whether the reason given by the district court for not then trying the case was a good one, and the reason advanced was not valid.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

The plan of the Act is to determine first whether what is seized is really food under the Act and is really adulterated as charged. If either is not true, the libel will be dismissed. If both are true, and a decree of condemnation is entered pursuant to the provisions of the Act, then, upon the conditions named in Section 304 (d), the article may be delivered to its owner to be brought into compliance with the statute. The statutory procedure should be precisely followed.

Sections 201 (f), 304 (a), 304 (d), 402 (a), Federal Food, Drug, and Cosmetic Act.

Golden N. Dagger, Special Assistant to the Attorney General, Department of Justice, Washington, D. C.; and Jim C. Smith, United States Attorney, Birmingham, Ala.; for petitioner.

Horace C. Wilkinson and Erle Pettus, both of Birmingham, Ala.; *contra*.  
Before SIBLEY, HOLMES, and WALLER, Circuit Judges.

<sup>12</sup> 95 F. (2d) 856; *aff'd* 306 U. S. 1.

<sup>13</sup> *Aetna Life Insurance Co. v. Haworth*, 300 U. S. 227, 241.

<sup>14</sup> *Great Atlantic & Pacific Tea Co. v. Grosjean*, 301 U. S. 412, 429.



[*Facts of Case*]

SIBLEY, Circuit Judge: The United States in 1940 brought five libels under the Federal Food and Drug and Cosmetic Act of 1938, to condemn five lots of "ladle butter" and "packing stock butter" transported in interstate commerce to Cloverleaf Butter Co., because adulterated in that it "consists in part of a filthy animal substance." On seizure, Cloverleaf Butter Co. claimed the material, denied the adulteration, prayed for a more definite statement or bill of particulars as to what sort of matter was intended to be relied on as constituting the adulteration; and as to whether all the containers seized were claimed to be so adulterated; and if not, which ones. In February, 1942, the cases were consolidated for trial, but instead of passing on the motions for a more definite statement or otherwise trying the case, an order was made to allow the claimant to take possession of the butter and renovate it. The United States filed a motion to vacate this order and stop its execution. This motion was pending, a stay being granted, till Oct. 4, 1943, when it was overruled and a new order made that the Marshal deliver the butter to the claimant at its renovating plant in Birmingham, for renovation, the identity of the several lots to be preserved, and the custody of the court being maintained, and full provision being made for the taking of samples by both sides before and after renovation, all at the expense of claimant. Jurisdiction was retained to dispose of the butter afterwards as if this order had not been granted. The United States petitioned this court for a writ of mandamus to compel the judge to vacate this order as being without authority of law, and to set a date certain for the trial of the case, an appeal not yet being available. We ordered that the judge show cause why the case should not be at once tried.

[*Reason for Judge's Order*]

The judge in his response admits the proceedings as above, and gives as his reason why he should not be required to proceed to a final trial of the libels, without waiting for a renovation of the butter therein described, facts which he states he understands are true; in brief that claimant has conducted for twenty-five years a regularly licensed plant in Birmingham for processing and renovating butter, its product being taxed under 26 U. S. C. A. § 2321, and regulated by 26 U. S. C. A. § 2325; that the

seized material is not transported nor about to be offered to the public as food, but is to be renovated and processed in the plant and then packed and branded and disposed of under the just cited law; that there is public need for butter, and if the material can as a finished product be so used it ought to be, rather than condemned; so that it is prudent and right to see what can be done with it before trying the libels for condemnation.

[*No Reason for Delaying Trial*]

We cannot by mandamus review or set aside the interlocutory order. Our only function at present is to decide whether the reason given for not presently trying the case is a good one. We do not think it is. The libels are filed expressly under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 301, and following. For its purposes "food" is defined as "Articles used for food or drink for man or other animals" and "Articles used for components of any such articles." § 321 (f). The introduction into interstate commerce of any food that is adulterated is forbidden by Section 331 (a). Food is declared by Section 342 (a) (3) to be adulterated if it "consists in whole or in part of any filthy matter." An adulterated article of food when introduced into interstate commerce may be seized for condemnation by libel. Section 334 (a). By Section 334 (d) any food condemned shall be disposed of as the court may direct, and if sold the proceeds go to the United States; "Provided, that after entry of the decree and upon payment of the costs of such proceeding and the execution of a good and sufficient bond . . . the court may be order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Chapter, etc." The Act thus provides for the saving from destruction of articles which ought to be saved, much as the judge has ordered here. It also provides in Section 334 (c) for sampling to ascertain the truth before trial. But the plan of the Act is to determine first whether what is seized is really food under the Act, and is really adulterated as alleged. If either is not true, the libel will be dismissed. If both are true, and decree is entered accordingly, then upon the conditions named in the Act the measures above quoted may be taken. We think the statutory proceedings ought to be precisely followed, and that no good reason is shown for further delaying



to rule on the motions for a more definite statement and to bring the matter to a final trial.

*[Opinion Certified to Judge for Guidance]*

Let a copy of this opinion be certified to the Judge for his guidance. A formal mandamus may hereafter be issued if necessary.

**Dissenting Opinion**

WALLER, Circuit Judge, dissenting: I do not take issue with what has been said in the majority opinion in this case, but I do take issue with the action of the Court in saying anything at all except to say "Petition denied." The opinion of this Court seems to correctly interpret the applicable part of Federal Food and Drug and Cosmetic Act, but the majority, in my view, has indulged in the vacuous pastime of writing an advisory opinion "for the guidance" of the Court below.

We were petitioned for a writ of mandamus—not for advice—and the petitioner has not shown itself to be entitled to such a writ. It is the universal rule that a relator in mandamus must positively show not only that a clear duty devolves upon the respondent to perform a duty but that relator has a clear right to the performance of that duty. The petitioner has wholly failed to show a clear right to performance of the alleged duty.

The United States Attorney filed the libels in July, 1940, alleging that the food products were "adulterated \* \* \* in that it consists in whole or in part of a filthy animal substance." It is not alleged that all of the cans of butter are adulterated, and nowhere were any facts alleged as to what the "filthy animal substance" was. Claimant promptly filed a motion for a more definite statement or for a bill of particulars. It was clearly entitled to have a bill of particulars showing whether all cans were adulterated and also what filthy matter was claimed to

be in the product sought to be condemned. The motion was filed July 16, 1940. The petitioner did not supply the bill of particulars, nor does the record show that it ever set the motion down for a hearing. It is difficult to see how claimant could prepare its defense in the absence of fuller information. The claimant has never answered. The case is not at issue, yet the United States Attorney is now shouting for a trial, and petitioning for a writ to require a trial when the case is not at issue and, for all the record shows, the delay is chargeable as much to him as to the claimant. Surely the Judge is not chargeable with the defect of petitioner's pleading in lack of specificity. The United States Attorney evidently was possessed of the information as to the alleged filthy animal substance because he now goes entirely out of the record and repeatedly asserts in his brief—which he surely knows is no substitute for pleading—that the butter contains maggots, dirt, hair, feather and maggot fat and other filthy matters.

The United States Attorney has not placed himself in position to insist that he has a clear right to have the respondent proceed to an immediate trial. Furthermore, he is seeking by mandamus to have this Court review an interlocutory order of the Court below. In this he succeeded. Mandamus is not a substitute for appeal. The action of the Court below may have been irregular, but no one is injured except perhaps the claimant. All costs of renovation are placed on it. Jurisdiction is retained. The Court can order renovated butter condemned as well as it can unrenovated butter. It is not being eaten while in custody of the Court.

Petitioner is not hurt but he hollered nevertheless.

I respectfully dissent.

**UNITED STATES v. 720 BOTTLES, MORE OR LESS, OF  
 AN ARTICLE LABELED IN PART: (BOTTLES): "2  
 FL. OZ. \* \* \* PLANTATION PURE VANILLA  
 EXTRACT FOR FLAVORING, PLANTA-  
 TION EXTRACT CORPORATION,  
 NEW YORK"**

United States District Court for the Eastern District of New York.  
 Miscellaneous 504. May 13, 1944. 3 F. R. D. 466.

In a seizure proceeding, a motion was made by the Government to vacate a notice of the taking of the oral deposition of employees of the Federal Se-



*U. S. v. 720 Bottles, etc., Plantation Pure Vanilla Extract etc.*

curity Agency, and for the production of books and records. The opinion of the committee which formulated the Federal Rules of Civil Procedure, that the rules were not thought to apply to proceedings under the Federal Food, Drug, and Cosmetic Act, constitutes a comment on the part of the best informed body and cannot be treated otherwise than with great respect.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Since the framers of the Federal Rules of Civil Procedure were of the opinion that they did not apply to seizure proceedings, the court should adopt that view in the absence of compelling reason to the contrary.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

Even if the committee's view were mistaken, the Government would still be in a position to urge that the expert testimony of its chemists should not be available to the claimant under the guise of discovery.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

Discovery as sanctioned by the Federal Food, Drug, and Cosmetic Act would not be appropriate in the instant case, because that which was sought appeared to consist of expert testimony on the part of chemists who had made analyses of samples of the commodity seized, and such analyses and the conclusions based thereon do not constitute the kind of evidence that one party should be required to disclose to his adversary in ordinary litigation.

Sections 304 (b), 304 (c), Federal Food, Drug, and Cosmetic Act.

Harold M. Kennedy, U. S. Attorney (Morris K. Siegel, Assistant U. S. Attorney, and Irvin Goldstein, Assistant Attorney General, of counsel), for libelant.

Louis Halle, for Plantation Extract Corp., intervenor.

[*Motion*]

BYERS, District Judge: Motion by the United States of America, as libelant, to vacate a notice of the taking of the oral deposition of employees of the Federal Security Agency, Food and Drug Administration, and for the production of books and records by them.

[*Seizure of Adulterated and Misbranded Vanilla Extract*]

This is a proceeding under the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. A. § 301 *et seq.*, seizure having been made under Section 334 because the subject-matter, namely, vanilla extract, is alleged to have been adulterated and misbranded.

[*Theory of Motion*]

The motion is made upon the theory that the proceeding, being deemed to be in Admiralty, is not governed by the Federal Rules of Civil Procedure, pursuant to which the notice of the taking of the depositions was given.

[*Statutory Provisions*]

The statute says (Section 334 (b) in part):

"The article shall be liable to seizure

by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury."

[*Federal Rules of Civil Procedure Not Applicable*]

Since the discovery sought by the claimant is a matter of procedure, it becomes apparent that the first and most important question is whether the Federal Rules of Civil Procedure govern a proceeding under this statute. Rule 81 applies, and paragraph (2) makes it clear that the Federal Rules govern appeals only,

"except to the extent that the practice in such proceedings is not set forth in statutes of the United States and has heretofore conformed to the practice in actions at law or suits in equity: \* \* \* forfeiture of property for violation of a statute of the United States."

The note appended by the Committee touching this subdivision is as follows:

"For examples of statutes which are preserved by paragraph (2) see: \* \* \* Title 21, § 14 (Pure Food and Drug Act—Condemnation of Adulterated or Misbranded Food; Procedure)."



The foregoing is understood to mean that, in the opinion of the Committee, the Federal Rules of Civil Procedure were not thought to apply to proceedings under the Pure Food and Drug Act; while that opinion is not to be extended beyond its proper scope, it constitutes a comment on the part of the best informed body, on the subject of the scope of the Federal Rules—namely, the Committee which formulated them—and, as such, cannot be treated otherwise than with great respect.

There is no present difficulty in disposing of this motion on the theory that discovery as sanctioned by the Federal Rules of Civil Procedure would not be appropriate to this case, because that which is sought to be elicited from the government witnesses doubtless consists of expert testimony on the part of chemists who have made analyses of samples of the commodity which has been seized, and it does not seem that such analyses and the conclusions based thereon constitute the kind of evidence that one party should be required to disclose to his adversary in ordinary litigation.

It is quite true that in most civil causes the Federal Rules intend one litigant shall be able to secure the help of his adversary in developing his own side of the case, but that customarily has to do with the facts

as observed by witnesses to a given occurrence or transaction; it does not apply to matters of expert testimony such as scientific data prepared by engineers. See *Lewis v. United Airlines, etc.*, 32 Fed. Supp. 21.

It is true that the latter case dealt with relief which was sought under Rule 30 (b), while the pending motion is upon the theory that no discovery whatever under the Federal Rules is proper in this proceeding.

The decision of the motion is that, since the framers of the Rules were of the opinion that they did not apply to such proceedings, this Court should adopt that view, in the absence of compelling reason to the contrary.

[No Compelling Reason for Contrary Holding]

One reason for believing that there is none such, is that, even if the foregoing view is mistaken, the government would still be in a position to urge that the expert testimony of its chemists should not be available to the claimant, under the guise of discovery.

*443 Cans, etc., v. U. S.*, 226 U. S. 172, is not thought to point to a contrary result.

[Motion Granted]

Motion granted. Settle order.

## FRESH GROWN PRESERVE CORPORATION v. UNITED STATES

United States Circuit Court of Appeals for the Sixth Circuit. No. 9713.  
May 31, 1944. 143 F. 2d 191.

In a seizure proceeding against a food product, a consent decree of condemnation was entered which provided for the release of the article to the claimant on the execution of a bond. The decree provided, among other things, that the claimant would not sell or ship the product in interstate commerce until the Federal Security Agency should have released it after examination. The bond covenanted that the principal and surety would abide by the decree. On motion by the Government to forfeit the bond on the ground that the claimant had not complied with the decree, it was held that the libel proceeding was not terminated with the entry of the decree of condemnation, and that the District Court had not intended to surrender its jurisdiction over the condemned food until the requirements of the decree had been fully met.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

The omission from the Act of specific directions for procedure on the bond in the event of breach was not fatal to the inherent right of the district court to proceed to judgment of forfeiture in the event of breach.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

An unexpressed intention of Congress to require a plenary or independent action as precedent to adjudication of liability upon the bond furnished



under Section 304 (d) can not be reasonably deduced from the manifest purpose and full context of the Act. It is more reasonable to assume that Congress intended that the district court retaining jurisdiction over the seized goods should retain also the right to declare and adjudicate a forfeiture on the bond.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Assimilating the procedure to admiralty practice, a court having jurisdiction of the principal cause possesses jurisdiction over all its incidents, and may by motion, attachment, or execution enforce its decree against all who become parties to the proceedings. Bonds, in intent and purpose, are stipulations in admiralty.

Sections 304 (b), 304 (d), Federal Food, Drug, and Cosmetic Act.

No issue of fact as to damages need be tried in a suit on a bond furnished under Section 304 (d), since such a bond is penal and not indemnatory in character and names the United States as obligee.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

In the absence of express or implied provisions to the contrary in a statute which prescribes the making of a bond, or in the bond itself, the full penalty for breach of the bond executed as a condition for a license or other privilege may be recovered where the obligee is a body politic.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

When by statute an agency of the United States is authorized to take a bond as assurance of compliance with law, there is no necessity that the statute expressly prescribe the conditions of the bond.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Were a material issue of fact presented by conflicting affidavits on motion to forfeit a bond for breach, either party would be entitled to a trial of the issue. But under Civil Procedure Rule 56, 28 U. S. C., following Section 723c, summary judgment may be granted if there is no genuine issue as to any material fact.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Since claimant's affidavit, on motion to forfeit bond for breach, admitted that claimant had violated the bond, and the charge of violation made by the Government was not denied by the claimant, liability on the bond attached on uncontroverted affidavits and summary judgment was properly entered.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Louis Halle, New York, N. Y. (Edmonds & Harter of Columbus, Ohio, and Halle, Halle & Rowen of New York, N. Y., on brief), for appellant.

R. J. O'Donnell, Columbus, Ohio (Calvin Crawford of Cincinnati, Ohio, R. J. O'Donnell of Columbus, Ohio, and Vincent A. Kleinfeld of Washington, D. C., on brief), for appellee.

Before SIMMONS, MARTIN and McALLISTER, Circuit Judges.

[*Jam Libeled as Adulterated*]

MARTIN, Circuit Judge: Charging adulteration and misbranding in violation of the Federal Food, Drug, and Cosmetic Act, the United States, by its attorney for the Southern District of Ohio, filed a libel against one hundred ninety-six cases, containing six cans each, of an article of food labeled under six assorted flavors as "Nature's Own Pure" blackberry, apricot, grapes, loganber-

ry, peach and raspberry jam. The libel alleged that the appellant, Fresh Grown Preserve Corporation, had transported the food in interstate commerce from Kingsland, New Jersey, to East Columbus, Ohio; and that the article was situated within the jurisdiction of the district court. It was averred that analysis showed the food article to be adulterated in violation of U. S. C. A., Title 21, Section 342, in that imitation blackberry,



apricot, grape, loganberry, peach and raspberry jam deficient in fruit had been substituted wholly, or in part, for such fruit jam, as defined in the Federal Register of September 5, 1940, Section 29000. The libellant charged further that the article was misbranded in violation of U. S. C. A., Title 21, Section 343 (a), in that the label "Pure Blackberry Jam" and the use of the word "Pure" in labeling the other flavors were false and misleading as applied to the article which was deficient in fruit. The misbranding was said to constitute imitation of another food; and failure to conform to the definition and standard of identity prescribed by applicable regulations (U. S. C. A., Title 21, Section 341) was averred. The libellant prayed for the issuance of appropriate process of attachment; for citation of all persons asserting title or claim to the article of food; for condemnation of the food product; for the entry of all appropriate orders; and for costs and general relief.

*[Consent Decree of Condemnation]*

On October 2, 1941, five and one-half months after this libel was filed, the district court entered a consent decree, approved by the United States Attorney and the appellant. The consent of the latter was evidenced by the official signature of its president to the following stipulation at the bottom of the decree: "The Fresh Grown Preserve Corporation, appearing herein as claimant and owner of the above mentioned canned jams, does hereby admit the truth of the allegations contained in the libel filed in the above entitled cause. It consents that the foregoing proposed decree be entered, the stipulations of which are hereby made a part of this consent."

Reciting this consent, the decree provided that the seized merchandise be condemned as forfeited to the United States of America.

*[Release to Claimant Under Bond]*

In awkwardly arranged language, the decree provided for the release of the seized food article to the claimant (appellant herein), upon its performance of all the condition of a bond in the penal sum of five hundred dollars, should such bond be executed by the claimant and delivered to the libellant within thirty days from the date of the decree. This bond was directed to be conditioned upon numerous undertakings and restrictions. Within thirty days from the entry of the decree, the claimant would

be required to reship the food to its warehouse at Lyndhurst, New Jersey, "there to be relabeled under the supervision of the Food and Drug Administration so that the same will comply with the requirements of the Food, Drug, and Cosmetic Act of June 25, 1938." The merchandise was to be kept intact for inspection by a representative of the United States Federal Security Agency, and records preserved as proof, to the satisfaction of the government's agent, of the identity of the food-stuff.

*[Inspection To Be Allowed Before Shipment]*

The positive mandate was written into the decree that the "claimant shall submit to the said Agency at the said warehouse for inspection all of the said aforementioned canned jams relabeled." The claimant was forbidden under any circumstances whatsoever to ship, sell or offer for sale in interstate commerce or otherwise for human consumption any part of the canned jams "until the United States Federal Security Agency, through its designated inspector or other representative shall have had free access thereto at the aforesaid warehouse in order to make whatever examination and test they may desire and shall have released such aforementioned canned jams for such sale and shipment." The claimant was required to abide the final decision of the representative of the Federal Agency, and should his decision be adverse, the entire lot or any portion of the canned goods not passing inspection was directed to be destroyed under his supervision without further order of the court. Provisions were made for the payment by claimant of the cost of the government inspection, for the disposition of the merchandise in compliance with state and federal law, and for the furnishing by claimant of satisfactory evidence that it had complied with the decree.

*[Covenant of Bond]*

Naming the United States of America as obligee, a bond with a copy of the district court decree annexed was executed by appellant with the Century Indemnity Company as surety, and was filed in the case on November 6, 1941. This bond contained the following covenant:

"NOW, THEREFORE, the condition of this obligation is such that if the above bounden Principal and its successors and assigns shall abide by and perform said decree aforesaid and any and all other decrees and orders of this Court



entered in the said cause, and shall not sell or otherwise dispose of said food contrary to the provisions of Food, Drug, and Cosmetic Act of June 25th, 1938, and amendments thereto, and all laws Federal and State thereto relating and shall not sell or dispose of said food until the United States Federal Security Agency through its designated inspector or other representative shall have released said food for sale and/or shipment, said bond to be approved by this Court, then this obligation to be void, and of no effect, otherwise to remain in full force and effect."

*[Motion for Forfeiture on Performance Bond]*

The United States, by its Attorney, filed a motion on March 22, 1943, for forfeiture on the performance bond on the ground that the claimant had not complied with the order of the Court. An affidavit of the Assistant United States Attorney was filed in support of the motion. The affiant asserted that the food article had not been relabeled in compliance with the decree of the court either within thirty days from its date or within the extended time granted. The affiant charged that the order of the district court had been "circumvented deliberately" by the claimant and that "a considerable number of cases of adulterated and misbranded jam and preserves were re-shipped in interstate commerce from Lyndhurst, New Jersey, or otherwise disposed of in their original condition as they had been returned to the factory of the Fresh Grown Preserve Corporation under bond for relabeling."

*[Defense]*

Leo Greenberg, vice president of the appellant corporation, filed on May 14, 1943, an affidavit in opposition to the motion of the United States Attorney. Certain correspondence between the New York office of the Federal Security Agency and the appellant and its attorney was attached to the Greenberg affidavit. The principal point made by appellant in this affidavit and the attached correspondence was that the merchandise subjected to seizure in the libel proceedings had been placed on the premises of appellant and held in readiness for relabeling in compliance with the decree, and that although numerous requests had been made of the Food and Drug Administration of New York to have its representative supervise the relabeling pursuant to the terms of the decree, the government agency had failed to send its representative

to supervise the relabeling. The affiant Greenberg further deposed that "during the month of February, 1943, the claimant relabeled the said merchandise as provided in the said decree, *except that such relabeling was not supervised by the Food and Drug Administration and that such failure to supervise such relabeling was not occasioned through any fault of the claimant.*" [Emphasis supplied.]

*[Forfeiture Declared]*

The district court, on June 3, 1943, filed a memorandum decision reciting that the motion of the United States had been heard and submitted "on the affidavits of the libellant and the claimant and the Court being fully advised in the premises finds that the motion should be sustained." On June 28, 1943, the district court entered a decree declaring a forfeiture on the bond.

*[Motion To Vacate Decree of Forfeiture]*

On July 27, 1943, appellant filed a motion for an order vacating the order of the district court entered June 28, 1943, and for reargument of the libellant's motion for judgment on the bond. In support of this motion, the attorney for appellant filed his own affidavit in which he stated: "Your deponent respectfully submits that the court was without jurisdiction to entertain this motion and to enter the order decreeing the payment of the bond for the reason that there is no provision in law, under the Federal Food, Drug, and Cosmetic Act, authorizing the entry of such judgment by motion in the original proceeding, and that any recovery on such bond, because of any claim of a violation of any of its terms, must be had in a separate proceeding to be instituted as is required in any other action at law for the recovery of monies."

*[Appeal from Decree of Forfeiture]*

This motion for reargument and for vacation of the decree was denied. The appeal to this court is from the decree of June 28, 1943, adjudging forfeiture on the performance bond.

*[Contention of Appellant]*

The main contention of the appellant is a reiteration of its argument in the district court that the court lacked jurisdiction to decree a forfeiture on the performance bond, a plenary action on the bond being asserted as essential to recovery. The argument is made that with the entry of what appellant terms "the final decree" providing for forfeiture of the condemned goods and their



return to the claimant upon filing bond pursuant to Section 334 (d) of Title 21, U. S. C. A., there was no cause pending before the court; that the decree contained no provision for forfeiture of the bond regardless of breach thereof; and that the Federal Food, Drug, and Cosmetic Act contains no provision for forfeiture of the bond and entry of judgment thereon "without an independent action being commenced for that purpose," and after trial of the issues in such action. The further point (which is considered unimportant) is made that no notice having been given the surety, the district court lacked power to adjudicate the surety's liability on the bond.

Citing *Four Hundred and Forty-three Cans of Frozen Egg Product v. United States*, 226 U. S. 172, 183, the appellant points to the distinction between a forfeiture proceeding under the Federal Food, Drug and Cosmetic Act and seizure under the Admiralty Law. It is true that the Supreme Court declared that while the statute directs that proceedings under the Pure Food Act shall conform to those in admiralty, as near as may be, the Congress did not intend to liken the proceedings to those in admiralty beyond the seizure of the property by process *in rem*, "then giving the case the character of a law action, with trial by jury if demanded and with the review already obtaining in actions at law."

*[Proceeding Not Terminated by Decree of Forfeiture]*

This principle is deemed irrelevant to the situation confronted here. The libel proceeding was certainly not terminated with the entry of the decree of forfeiture, which elaborately provided for future steps to be taken before the reconditioned or relabeled goods were authorized to be released without restriction to the claimant. The district court obviously did not intend to surrender its jurisdiction over the condemned food article, until the requirements of its decree should be fully met. The statute, U. S. C. A., Title 21, Section 334 (d), expressly provides that after entry of the decree of condemnation, and payment of the costs of the proceeding and the execution of the good and sufficient bond conditioned that the condemned food article shall not be sold or disposed of contrary to the provisions of the Federal Food, Drug, and Cosmetic Act or the laws of any state or territory in which sold, the court may by order direct that the condemned article be deliv-

ered to the owner for destruction or to be brought into compliance with the provisions of the Act under the supervision of an officer or employee duly designated by the Federal Security Administrator, and that the expenses of such supervision shall be paid by the person obtaining release of the article under bond.

*[Jurisdiction Over Condemned Food Not Lost When Performance Bond Is Accepted]*

The omission from the statute of specific directions for procedure on the bond in the event of breach of its conditions is not fatal to the inherent right of the court to proceed to judgment of forfeiture in the event of breach. No restriction upon such course is indicated in the statute. There could be no point to acceptance of a bond in lieu of goods seized and condemned pursuant to the statute and temporarily returned to the custody of the owner upon prescribed conditions unless liability upon the bond could be adjudicated in the same proceeding in the event of a failure of the obligor to fulfill the conditions of the decree. The clear intent of the statute to withdraw from commerce food unfit for human consumption would be thwarted should the narrow interpretation be adopted that the district court loses jurisdiction over a condemned food article when a performance bond is accepted conditioned on the relabeling or reconditioning of the misbranded or deleterious goods under government supervision. We find no justification for such narrow construction in the language of the statute itself.

*[Court Retains Right To Declare Forfeiture on Bond]*

Nor can an unexpressed intention of Congress to require a plenary or independent action as precedent to adjudication of liability upon the performance bond be reasonably deduced from the manifest purpose and full context of the statute. In the absence of prescribed procedure for the fixation of liability for non-performance of the performance bond, it is more reasonable to assume that Congress intended that the district court retaining jurisdiction over the seized goods should retain also the right to declare and adjudicate a forfeiture on the bond. What reasonable object would be served by trying in a separate action and perhaps in a different court the issue of whether the owner of a condemned goods



had properly relabeled or reprocessed the articles in conformity with the decree of the court of original jurisdiction which condemned the merchandise as violative of the Federal statute? No such repetitive or round-about procedure should be presumed as within the intent of Congress.

*[Court Possesses Jurisdiction Over Incidents of Principal Cause]*

Assimilating the procedure here to admiralty practice, a court having jurisdiction of the principal cause, possesses jurisdiction over all its incidents, and may by motion, attachment, or execution enforce its decrees against all who become parties to the proceedings. Bonds, in intent and purpose, are stipulations in the admiralty. *Munks v. Jackson*, 66 Fed. 571, 574.

*[No Issue as to Damages]*

No issue of fact as to damages need be tried in the instant case for the reason that the bond filed herein is penal and not indemnatory in character and names the United States of America as obligee.

*[Full Penalty Recoverable]*

It is settled law that in the absence of express or implied provisions to the contrary in a statute which prescribes the making of bond, or in the bond itself, the full penalty for breach of the bond executed as a condition for license or other privilege may be recovered where the obligee is a body politic. *Clark v. Barnard*, 108 U. S. 436; *United States v. Dieckerhoff*, 202 U. S. 302; *Illinois Surety Co. v. United States*, 229 Fed. 527 (C. C. A. 2); *Eagle Indemnity Co. v. United States*, 22 F. (2d) 388 (C. C. A. 4). When by statute an agency of the United States Government is authorized to take bond as assurance of compliance with law, there is no necessity that the statute expressly prescribe the conditions of the bond. *Illinois Surety Co. v. United States*, *supra*; *Moses v. United States*, 166 U. S. 571.

*[Judgment on Affidavits Proper When No Issue of Fact]*

Appellant contends further that its right to a trial of contested issues was denied by the entry of judgment on the bond merely on motion supported and opposed by affidavits. This argument would rest on solid

ground if the record revealed a factual basis for it. Were a material issue of fact presented by conflicting affidavits, either party would be clearly entitled to introduce its own witnesses and to cross examine those of its opponent. But under Civil Procedure Rule 56 summary judgment on motion on appropriate notice shall be rendered forthwith if the pleadings, depositions and admissions on file, *together with the affidavits*, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.

As stated earlier in this opinion, the vice president of the appellant corporation admitted in his affidavit that appellant relabeled the condemned articles of food without supervision by a representative of the Federal Security Agency. This proscribed relabeling was in direct contravention of the decree of the district court and of the provisions of the statute and the conditions of the performance bond. Moreover, the charge in the affidavit of the United States Attorney that a considerable number of cases of the misbranded food articles had been reshipped in interstate commerce was not denied by appellant. Liability on the bond therefore attached on uncontroverted affidavits, and summary judgment was properly entered under Civil Procedure Rule 56.

*[Uncooperative Attitude of Agency Affords No Right To Violate Law]*

It should be observed that the attitude of the Federal Security Agency in not sending its representative to supervise the relabeling of appellant's seized and condemned food articles was not cooperative and is not to be commended. The course pursued by the agency appears to have been either arbitrary or neglectful, but this afforded appellant no right to violate the law. The appellant's appropriate course would have been to move the district court for an order directing the Federal Agency to perform forthwith its function under the decree. The aid of the court was not thus invoked. To the contrary, appellant deliberately violated the court's order by its own admission.

*[Order Affirmed]*

The order of the district court of June 28, 1943, is affirmed.



FRESH GROWN PRESERVES CORPORATION AND THE  
CENTURY INDEMNITY COMPANY  
v. UNITED STATES

United States Circuit Court of Appeals for the Fourth Circuit. No. 5252.  
July 31, 1944. 144 F. 2d 136.

In a suit to recover full penalty of a bond executed by claimants to repossess goods condemned under the Federal Food, Drug, and Cosmetic Act, the lower court's finding that the conditions of the bond had not been substantially complied with was overwhelmingly supported by the evidence.

Sections 304 (a), 304 (d), Federal Food, Drug, and Cosmetic Act.

The bond given by claimants to obtain possession of the condemned product for salvaging purposes was a penal bond, not an indemnity one.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Where a bond is given to a public body as a condition of a privilege or conditioned on compliance with law, the full penalty of the bond may be recovered for a breach in the absence of statutory provision to the contrary.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Louis Halle (Douglas McKay on brief), for appellants.

Arthur A. Dickerman, Attorney, Federal Security Agency, and Henry H. Edens, Assistant U. S. Attorney (Claud N. Sapp, U. S. Attorney, on brief), for appellee.

Before PARKER, DOBIE and NORTHCOTT, Circuit Judges.

*[Action To Recover Bond Penalty]*

NORTHCOTT, Circuit Judge: This is an action brought in the District Court of the United States for the Eastern District of South Carolina in September 1942, by the appellee, United States of America, here referred to as the plaintiff, seeking to recover the full penalty of a bond in the sum of \$1,000.00 given by one of the appellants, Fresh Grown Preserve Corporation, here referred to as a defendant. The appellant The Century Indemnity Company, here referred to as a defendant, was the surety on the bond.

*[Appeal from Judgment for Plaintiff]*

In December 1943, a trial was had and in February 1944 the trial judge handed down an opinion finding the facts and stating his conclusions of law holding for the plaintiff. Judgment was entered in accordance with this finding from which judgment this appeal was brought.

*[Shipment of Preserves]*

In February 1941 the defendant Fresh Grown Preserve Corporation shipped to the Quartermaster at Fort Jackson, South Carolina, 600 cases, six cans in each case, of an article, labeled in part "Nature's Own Pure Strawberry Preserve" \* \* \* also "Blackberry, Peach and Cherry."

*[Defendant Asked To Reclaim and Relabel Goods]*

On April 16, 1941, a libel was filed, in the District Court of the United States for the Eastern District of South Carolina, entitled "*United States of America, Libellant, v. 600 Cases, more or less,*" and the goods were seized. On May 14, 1941, no answer having been filed, an order was entered condemning said goods and directing their destruction by the Marshal. Before all of said goods had been destroyed, the defendant Fresh Grown Preserve Corporation intervened in the libel proceeding as the owner and shipper of said goods and filed a claim and a stipulation admitting the allegations of the libel, consenting to a decree of condemnation, and asking to be allowed to reclaim such of the goods as had not been previously destroyed for the purpose of relabeling them before putting them into the channels of commerce again.

*[Conditions of Bond Required by Decree]*

On September 23, 1941, the court entered an order holding and decreeing that said goods were adulterated and were misbranded as alleged and ordering the forfeiture thereof; but providing that, in case the claimant should, within thirty days from the date of said decree, pay all the costs of said proceeding and execute and deliver to



*Fresh Grown Preserves Corp. v. U. S.*

the libellant a good and sufficient bond in the sum of \$1,000.00, conditioned as provided in said decree, the condemned goods should be released to the claimant.

The conditions of said bond or undertaking as required by said decree were as follows:

1. That claimant would, at its own cost and within thirty days, cause said libeled goods to be reshipped to the warehouse of the claimant in New Jersey and there relabeled under the supervision of the Food and Drug Administration so as to comply with the requirements of the Food, Drug, and Cosmetic Act of June 25, 1938.

2. That the claimant would retain the entire lot of condemned goods intact for examination or inspection by a representative of the United States Federal Security Agency, and at all times maintain necessary records or other proof to identify said goods to the satisfaction of said representative.

3. That the claimant would notify the Federal Security Agency of its purpose to do so and then submit to the Agency's representative all of said goods at claimant's warehouse for the purpose of examination and inspection.

4. That the claimant would not, under any circumstances, ship or sell, or offer for shipment or sale, for human consumption, any part of said goods until a representative of said Federal Security Agency had been given free access to said goods for the purpose of inspection and he had released the same for sale.

5. That the claimant would pay \$14.00 per day as salary or wages and \$5.00 per day as subsistence and expenses for each day a representative of the Federal Security Agency should be engaged in supervising or inspecting the relabeling of said goods.

6. That the claimant would abide by the decision of the representative of said Agency as to the proper relabeling of said goods, which decision should be final.

7. That the claimant would furnish evidence, by affidavit or otherwise, satisfactory to the Federal Security Agency, as to the relabeling of said goods, and file the same with the Clerk of this Court.

The bond was duly executed by the defendant Fresh Grown Preserve Corporation and by the defendant indemnity company as surety on September 30, 1941, and filed in the court November 4, 1941. 217 cases of the condemned goods were shipped from Columbia, South Carolina, to the defendant Preserve Corporation on November

2, 1941, and they were in due course received by said defendant at its warehouse in Lynhurst, New Jersey.

*[Stipulation]*

There was no further action in the libel proceeding until August 14, 1942, when appellants filed with the court a signed written stipulation, as follows:

"IT IS HEREBY STIPULATED AND CONSENTED that the decree heretofore entered on the above entitled cause on the 23rd day of September, 1941, be amended to further provide: That the time for the claimant herein to relabel the merchandise in conformity with the decree entered herein, be extended to the 1st day of October, 1942, and that this extension is conditioned upon the claimant furnishing to the Food and Drug Division of the Federal Security Agency satisfactory evidence as to the disposition of the relabeled goods by furnishing said Food and Drug Division a duplicate of the invoice of the sale of such merchandise which said invoice shall contain the amount and description of the merchandise and the name and address of the purchaser.

"IT IS FURTHER STIPULATED that in the event that the said merchandise is not relabeled within the period of time as provided for in this stipulation, the claimant will not request a further extension."

*[Supplemental Order]*

On the date of the filing of this stipulation the court below entered a supplemental order in the libel proceeding reciting that the merchandise in question had been condemned and forfeited but giving leave to the claimant to repossess certain of said merchandise; that the claimant had not carried out all of the conditions prescribed in the order of the court below that were made the condition of said bond and further ordering that "the time for relabeling (said goods) in a manner satisfactory to the said Food and Drug Division and carrying out the other provisions relative to said relabeling and satisfying the said Division, be extended to the 1st day of October 1942," subject to the following proviso:

\* \* \* that the above extension is contingent upon the claimant paying all costs, disbursements and expenses due to or incurred by the Clerk of this court and by the Marshal of this court in connection with this cause \* \* \* in full within ten days from the date hereof. Upon failure of such payment within such time then



the extension hereinabove granted in this order shall become null and void and the District Attorney is directed to institute suit for the enforcement of the terms of the bond on file in this cause forthwith \* \* \*."

*[Costs Not Paid within Specified Time;  
Action Brought]*

The costs required to be paid as a condition precedent to the extension of time asked for were not paid within the time specified in the last order of the court below. Thereafter, this action was brought.

*[Questions Involved in Appeal]*

Two questions are involved in the appeal: (1) Were the conditions of the bond breached? (2) Was the bond a penal bond or an indemnity bond?

*[Conditions of Original Bond Were Breached]*

That the conditions of the bond as originally given were breached is not open to dispute. The Preserve Corporation did not retain the entire lot of condemned goods intact for examination or inspection and did not notify the Federal Security Agency when they were ready to relabel the goods reclaimed. The Preserve Corporation also offered for shipment and sale part of said goods before a representative of the Federal Security Agency had been given free access to them for the purposes of inspection and did not furnish satisfactory evidence as to the relabeling of said goods.

It is claimed on behalf of the Preserve Corporation that the conditions of the bond were substantially complied with, but the judge below found this not to be a fact and we are of the opinion that his finding is not only based upon substantial evidence but is overwhelmingly supported by the evidence.

The Preserve Corporation claims to have relabeled the goods within thirty days after they were received but not under the supervision of the Food and Drug Administration, but that the Food and Drug Administration adopted the view that the relabeling had been properly done. As pointed out by the judge below in his able opinion it is not probable that if the relabeling had already been done the Preserve Corporation would have, months later, in August 1942, filed a stipulation asking for a further extension of time in which to do the relabeling. Upon this point and considering other

evidence the judge below found against the Preserve Corporation defendant.

*[Costs Admittedly Not Paid Within Time Specified]*

It is also admitted that the costs, the payment of which within ten days from the date of the order of August 14, 1942, was required by said order, were not paid within the time specified and as again pointed out by the judge below this failure to comply with the conditions of the order as expressly stated in the order made null and void the privileges granted under the order to the Preserve Corporation. The record discloses that a few cases of the goods were destroyed or damaged.

The Preserve Corporation contends that the order of August 14, 1942, was a waiver by the Government of any breach of the conditions of the bond that had occurred prior thereto but do not contend that they paid the costs within the time specified in the order to make the decree of August 14, 1942, effective.

The whole history of what happened, as shown by the record, makes a picture of repeated efforts on the part of the Government, its attorneys and agents to aid the Preserve Corporation in reclaiming the goods and just as many negligent acts on the part of the Preserve Corporation to avoid complying with the conditions prescribed by the court. In fact very few of the conditions of the bond or the requirements made in the court orders were strictly complied with by the Preserve Corporation and there seems to be no room for excusing their course of conduct.

The conditions of the bond were breached and the conditions of the court order excusing these breaches were not complied with.

*[Bond was Penal Bond, Not Indemnity Bond]*

On the second question the court below held that the bond was a penal bond and not an indemnity one. In this holding the judge below was clearly right. We had occasion to discuss this question in *Eagle Indemnity Co. v. United States*, 22 F. 2d 388, where we distinguished the case of *United States v. Zerbey*, 271 U. S. 322, chiefly relied upon by the defendants. The condition as to the payment of certain money was, of course, an indemnifying one but the breach of that condition is not charged.



*[Full Penalty May Be Recovered for Breach]*

The authorities are clear that where a bond is given to a public body as a condition of a privilege or conditioned on compliance with law, the full penalty of such bond may be recovered for a breach thereof, in the absence of statutory provision to the contrary.

*Clarke v. Barnard*, 108 U. S. 436.

*United States v. Dieckerhoff*, 202 U. S. 302.

*Eagle Indemnity Co. v. United States*, *supra*.

In *United States v. Dieckerhoff*, *supra*, the court said:

"But we think the purpose of the statute and the purpose of the requirement in the bond provided for therein, and the one given in this case, was to secure the performance of the duty imposed of returning the package or packages, where an importer availed himself of the privilege of withdrawing merchandise from the custody of the governmental officials before it has been examined and appraised. \* \* \*, we think it was the intention

of the law to provide specific damages to be recovered upon the nonperformance of the duty imposed, and to secure a prompt and faithful discharge of which the statute provides for the giving of a bond.

"We think such undertaking, for this manner of discharging this duty, or paying the value stipulated, was intended to and does relieve the government from the necessity of showing any actual damage or loss."

The Preserve Corporation was violating the law in shipping adulterated goods and showed no appreciation of the various efforts made to assist it in reclaiming and reconditioning the goods.

*[Judgment Affirmed]*

The findings of the judge below that the conditions of the bond were breached and that the bond was a penal one were correct and the judgment of the court below is accordingly affirmed.

*Affirmed.*

---

FRED B. COLLIER AND DIANNE I. COLLIER (NU-BASIC  
PRODUCTS CO.) v. PAUL V. McNUTT, FEDERAL  
SECURITY ADMINISTRATOR, ET AL.

United States District Court for the District of Columbia. November 7, 1944.  
Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act,  
Drugs and Devices (No. 2140) Issued April 1948.

Complainants sought to restrain the defendants from instituting legal proceedings under the Act with respect to complainants' drug product. The court denied complainants' motion for a preliminary injunction, and granted defendants' motion to dismiss and for summary judgment. The court concluded that the institution of multiple seizure suits was authorized inasmuch as the Commissioner of Food and Drugs, to whom such authority had been delegated by the Federal Security Administrator, had determined that he had probable cause to believe that the labeling of the product was in a material respect misleading to the injury or damage of the purchaser or consumer.

Sections 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

The court further concluded that the petition did not disclose any cause of action against the defendants, officials of the Federal Security Agency, since they were not authorized to institute suits in any court of the United States, and there was no mandatory duty vested in United States Attorneys or the Department of Justice to institute suits on the recommendation of the defendants.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The court further concluded that since the petition sought to restrain officials of the Federal Government from performing their statutory functions, the suit was against the United States, which had not consented to be sued, and the court did not have jurisdiction of the subject matter.

Section 304. (a), Federal Food, Drug, and Cosmetic Act.



**Findings of Fact and Conclusions of Law**

MATTHEW F. MCGUIRE, District Judge: This cause having come on to be heard on plaintiffs' motion for a preliminary injunction, and defendants' motion to dismiss the action and for summary judgment, the Court hereby files its Findings of Fact and Conclusions of Law as follows:

**The Court Finds**

1. The plaintiffs are, and were during the times mentioned in the petition for injunction, the owners of the Nu-Basic Products Company, which manufactures and sells in interstate commerce a drug product known as Pso-Ridisal for external use for diseases of the skin.

2. The said drug consists of a mineral oil emulsion, sulfanilamide, carbolic acid (phenol), and other ingredients, and has been introduced into interstate commerce under the names Sulfa-Seb and Sulfa-Ped, as well as under the name Pso-Ridisal.

3. On January 21, 1942, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed by the Government under the Federal Food, Drug, and Cosmetic Act in the United States District Court for the Northern District of Illinois. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, and by consent a decree of condemnation based on said misbranding was entered on April 12, 1944.

4. On January 28, 1944, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, said action was thereafter removed to the United States District Court for the Northern District of Illinois, and said article so seized was condemned by consent decree of condemnation based on said misbranding on April 26, 1944.

5. On November 10, 1943, shipments of said drug bearing the names Sulfa-Seb and Sulfa-Ped were seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading and

because its labeling failed to bear adequate warnings against unsafe dosage or methods of use in a manner and form necessary for the protection of users. After trial, the said Court, on April 3, 1944, entered a decree based on said false and misleading labeling condemning the labeling of said drug.

6. After the entry of the decrees above mentioned, applications were made by plaintiffs herein to the courts in which said actions had been filed praying that the seized articles be delivered to them to be brought into compliance with the provisions of the Federal Food, Drug, and Cosmetic Act under the supervision of an officer or employee of the Food and Drug Administration, which applications were granted upon the execution of sufficient bond conditioned as required by law. Thereafter, the plaintiffs herein submitted to the Food and Drug Administration for approval a proposed form of labeling to accompany the seized articles, which form of labeling the Food and Drug Administration, after due consideration, did not approve.

7. Thereafter, the plaintiffs herein continued distributing its product in interstate commerce under the name Pso-Ridisal accompanied by labeling differing in minor respects from that which had accompanied the said drug involved in the actions above mentioned.

8. On or about June 13, 1941, the Federal Security Administrator delegated to the Commissioner of Food and Drugs authority to make determinations of probable cause under Section 304 (a) of the said Act (21 U. S. C. 334 (a)).

9. On July 29, 1944, the Commissioner of Food and Drugs determined that he had probable cause to believe, and that he did believe, on the basis of facts found by employees and officials of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer. Thereafter, a number of seizures of said drug with such labeling were made pursuant to libels of information filed in different district courts of the United States.

10. The plaintiffs herein, from the filing of said libel actions last above mentioned until the argument on plaintiffs' motion for a preliminary injunction and defendants' motion to dismiss this action and for summary judgment, did not, pursuant to Section 304 (b) of the Federal Food, Drug,



and Cosmetic Act (21 U. S. C. 334 (b)), apply to the court of one jurisdiction wherein one of said libel actions had been brought for an order consolidating all of said libel actions for trial in a district selected by the plaintiffs herein where one of such libel actions was pending.

11. One of said seizure actions last above mentioned was commenced by the Government in the United States District Court for the Western District of Missouri, entitled *United States v. 1233 Bottles Pso-Ridisal*. The plaintiffs herein appeared as claimants in said action and by motion filed on or about September 8, 1944, sought to have said action dismissed on the ground that other seizure actions involving said drug and founded on the same or similar allegations of misbranding were already pending in other district courts of the United States. The said District Court denied said application on September 16, 1944.

12. On or about September 8, 1944, the plaintiffs herein filed in the United States District Court for the Western District of Missouri an action entitled *Fred B. Collier et al. v. The United States of America, Federal Food and Drug Administration*, praying an injunction restraining the further seizure of shipments of said drug. Said action was dismissed by said District Court on plaintiffs' motion on September 9, 1944.

13. On or about September 16, 1944, the plaintiffs herein filed an action in the United States District Court for the Northern District of Illinois, entitled *Fred B. Collier et al. v. Paul V. McNutt, Federal Security Administrator*, praying that said Administrator be enjoined from instituting a new libel proceedings against said drug Pso-Ridisal and from harassing or interfering with the plaintiffs' business. Said action was dismissed on motion of the plaintiffs on or about September 29, 1944.

14. On or about September 20, 1944, the plaintiffs herein filed a petition in the United States District Court for the District of Columbia against the defendants herein seeking to restrain and enjoin them from instituting new libel proceedings and from further seizures of the product Pso-Ridisal, and from harassing and interfering with plaintiffs' operation of their business and the business of their distributors and dealers and from instituting any action based upon the same alleged misbranding which was the subject matter of the proceedings already instituted against the plaintiffs' said

product; and prayed that a preliminary injunction be granted.

15. On or about October 16, 1944, the defendants herein moved to dismiss this action and for summary judgment on the grounds that the petition of plaintiffs herein failed to state facts which entitled plaintiffs to the relief sought therein, and that this Court did not have jurisdiction of the subject matter of this action.

#### The Court Files the Following Conclusions of Law

1. On or about June 13, 1941, the Federal Security Administrator, pursuant to the authority vested in him by law, delegated to the Commissioner of Food and Drugs, Federal Security Agency, authority to make determinations of probable cause contemplated by Section 304 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (a)).

2. The institution of multiple libel for condemnation actions against plaintiffs' product Pso-Ridisal was authorized by law inasmuch as the Commissioner of Food and Drugs of the Federal Security Agency had determined, pursuant to said Section 304 (a) of said Act (21 U. S. C. 334 (a)), that he had probable cause to believe and that he did believe, from facts found by officers and employees of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer.

3. The actions of defendants complained of by plaintiffs herein were not illegal, were not in excess of the authority vested in defendants by law, and did not constitute an abuse of lawful duty.

4. The petition filed by plaintiffs herein does not disclose any cause of action against the defendants named therein since said defendants do not and are not authorized to institute libel for condemnation or other suits in any court of the United States, and there is no mandatory duty vested in United States Attorneys or the Department of Justice to institute libel for condemnation or other suits on referral by or recommendation of defendants.

5. The plaintiffs herein have not established that they have suffered or will suffer any irreparable or legal injury by the institution of libel for condemnation actions under the Federal Food, Drug, and Cosmetic Act against their product Pso-Ridisal.



6. Since the petition filed by plaintiffs herein sought to restrain defendants, officials of the Federal Government, from performing their statutory functions, the action instituted by plaintiffs herein was a suit against the United States which had not consented to be sued, and this Court does not have jurisdiction of the subject matter of this action.

7. The petition filed by plaintiffs herein establishes no grounds for equitable relief

and fails to state facts which entitle the plaintiffs to the relief sought by them.

8. The motion made by plaintiffs herein for a preliminary injunction should be denied.

9. The motion made by defendants herein to dismiss this action and for summary judgment should be granted.

Let the foregoing Findings of Fact and Conclusions of Law be filed, and order and decree be entered accordingly.

---

**JOHN T. BOWMAN, MASTER OF S. S. JAMES J. HILL v.  
ALLEN T. RETZLAFF, BALTIMORE STATION,  
FOOD AND DRUG ADMINISTRATION, OF  
FEDERAL SECURITY AGENCY, AND  
GEORGE T. CROMWELL, COLLECTOR OF CUSTOMS, PORT OF  
BALTIMORE**

United States District Court for the District of Maryland. No. 2894.

April 4, 1946. 65 F. Supp. 265.

A suit was instituted to enjoin the enforcement of an order requiring the exportation or destruction under customs supervision of wheat theretofore provisionally entered for importation into the United States. If the order of the Collector was not within the grant of statutory power, it should be enjoined, even though the statute does not provide for judicial review.

Section 801 (a), Federal Food, Drug, and Cosmetic Act.

The ultimate question was whether the decomposition of the wheat was so extensive as to render the grain unfit for food; and it could not be said that the determination of the Federal Security Administrator was not supported by substantial evidence.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

It was important that the administrative action had been taken in the field of importation, in which the power of Congress is exclusive and absolute.

Section 801 (b), Federal Food, Drug, and Cosmetic Act.

Where the owner of wheat refused entry into the country because of decomposition requested permission to dry the grain and sell it as poultry feed, and the Administrator refused to permit such action because it would not be safe, the scientific question was not free from doubt, but the decision of the Administrator was not arbitrary or capricious.

Section 801 (b), Federal Food, Drug, and Cosmetic Act.

The statute (Section 801) accords a hearing only after notice to the importer with respect to samples to determine whether the commodity is properly importable. At the hearing, the only right accorded to the importer is "to introduce testimony." The statute does not provide for a further hearing with respect to whether a food which is refused entry because of decomposition may be used for some other purpose than for human consumption.

Section 801 (a), Federal Food, Drug, and Cosmetic Act.

Section 801, as distinguished from other sections of the Act, does not provide for judicial review, and creates no personal Federal rights as the



basis for judicial review as long as the Administrator acts within the scope of his authority.

Section 801 (a), Federal Food, Drug, and Cosmetic Act.

[*Nature of Proceeding*]

CHESNUT, District Judge: In this case the master of the SS "James J. Hill" seeks an injunction against the enforcement of an order of Gilbert A. Dailey, Collector of the Port of Baltimore which required that 40,843 bushels of Canadian wheat heretofore provisionally entered for importation into the United States "must be exported, or destroyed, under custom supervision." The respondents are George T. Cromwell, Collector of Customs (successor to Gilbert A. Dailey) and Allen T. Retslaff, Chief of the Baltimore Station Food and Drug Administration of Federal Security Agency. They have answered justifying the order under Section 801 of the Federal Food, Drug, and Cosmetic Act of 1938 (21 U. S. C. A., s. 381), which deals with imports and exports.

Section 381 (so far as here material) provides that the Secretary of the Treasury shall deliver to the Federal Security Administrator samples of food offered for import into the United States, giving notice thereof to the owner or the consignee, "who may appear before the Federal Security Administrator and have the right to introduce testimony." If it is found that the article is "adulterated" "then such article shall be refused admission," and "unless such article is exported by the consignee within three months, it must be destroyed." By Section 342 (a) "food shall be deemed adulterated (3) if it consists in whole or in part of any filthy, putrid or *decomposed substance or if it is otherwise unfit for food.*" (Italics supplied.)

[*Contentions of the Parties*]

The position of the respondents is that in due course they have administratively determined that the wheat was unfit for food. The complainant attacks this position on two grounds: (1) that there was no substantial evidence before the respondents that the wheat was unfit for food and that their action is therefore arbitrary and capricious; and (2) that the Federal Security Administrator did not afford the plaintiff a fair hearing. Extended testimony was heard in court upon these issues and the case taken under advisement. After consideration I have reached the conclusion that the injunction applied for must be denied and the complaint dismissed.

[*Material Facts*]

I find the material facts to be as follows:

1. Prior to September 13, 1945, about 40,000 bushels of Canadian wheat were shipped by rail from Canada to Baltimore and there transshipped to the SS James J. Hill, a Government owned vessel. The wheat was consigned to an agency of the French Government at Casablanca, Morocco. The "Hill" sailed from Baltimore on September 13, 1945. The next morning it was discovered that there were ten feet of water in No. 1 hold, where the wheat was stowed, by reason, as it was later found, of an influx of water through a plumbing fixture which ought to have been blocked off when the vessel was not being used as a troop-carrier but which had been opened while the vessel was in port. The "Hill" proceeded to Hampton Roads, Virginia, where it found sufficient port facilities unavailable and consequently returned to Baltimore, arriving September 16, 1945. Discharge of all grain from the watered hold was immediately undertaken and the grain was entered at the Custom House at Baltimore by John F. Connor, a broker acting on behalf of the owner of the grain.

2. On September 24, 1945, the Collector of Customs served on Connor an order requiring the wheat to be held intact pending analysis of samples and advising that failure of the goods to comply with the requirements of the Food and Drug Act would result in an order for its exportation or destruction. The next day the Chief of the Baltimore Station Food and Drug Administration notified Connor in writing that inspection and analysis of the samples showed the wheat to be adulterated within the meaning of Section 402 (a) of the Food, Drug, and Cosmetic Act (21 U. S. C. A., s. 342 (a)) since it consisted in whole or in part of a filthy, putrid or decomposed substance, or was otherwise unfit for food. "Product is water damaged; grains hot and sour." The notice fixed a hearing date three days later "at which time and place you may be present and submit testimony, or at or before which time you may file a statement in writing."

[*Wheat Admittedly Unfit*]

3. It seems to have been conceded at that hearing as at the hearing in this court that



the wheat in its then condition was unfit for importation. On September 27, 1945, Connor made application for the release of 5,000 bags of wheat found to be undamaged by water and also for permission to recondition the damaged wheat by blowing, cleaning and drying and thus stopping further decomposition and deterioration. This permission was granted but with the following condition:

*[Condition of Release]*

"However, before issuing conditional release providing for final reconditioning and disposition of the damaged wheat it must be clearly understood just how you plan to accomplish this, for which purpose we are enclosing another blank application in duplicate. On receipt of this application stating the purpose to which the wheat is to be put after reconditioning and also outlining the method to be used in reconditioning, we shall issue the conditional release."

*[Pertinent Regulation]*

4. Regulations have been published for administration of the Act. No. 2.309 provides for relabeling or reconditioning an article to bring it within compliance with the Act. It provides that the owner or consignee may make request in writing for such reconditioning or other action to render the article not a food within the meaning of the Act. "Such request shall propose the labeling to be used and any other act to be done for such purpose and shall specify the time and place when such labeling or other act is to be done." If and when it has been done and in its changed condition approved by the Administrator the article may be released from detention.

*[Request for Release]*

5. It appears that the owner or consignee in this case did not make formal written application but did informally and by correspondence with the Administrator request the release of the wheat, then in process of being dried out, for use as poultry food, and submitting an offer for the purchase of the dried wheat from a dealer in poultry foods on November 16, 1945; and on November 27, 1945 attorneys for the owner requested a hearing by the Administrator with an opportunity to submit testimony "as to the present condition of the damaged wheat, and particularly on the question of the fitness of said wheat for animal food"; and stating that they had consulted the Department of Poultry Husbandry at the University of Maryland, College Park, Maryland, and submitted samples of the re-

conditioned grain in order that it could be carefully examined and tested to determine its availability as poultry food; and that this proposed test would cover a period of two or three weeks at which time the results of the test would be submitted. The Administrator replied on November 30, 1945, that a hearing under the Act had already been given and that the request for the use of the wheat as poultry feed was denied and declining to accept the invitation to participate in the controlled feeding tests.

6. On December 11, 1945, the Collector of Customs passed the formal order for the destruction or exportation of the damaged wheat to be complied within three months. The notice stated "part of the lot has been dried since detention. Examination of the dried portion of this lot indicates it to be unfit for food of any kind. Undried portion is decomposed or hot and sour."

7. Some further informal negotiations or consultation ensued between the parties with a final letter from Mr. L. D. Elliott, Assistant Commissioner of Food and Drugs at Washington, dated January 9, 1946, which stated in part:

"As was further pointed out to him (Mr. Robert Williams, attorney for the owners) this Administration cannot agree to the release of this damaged grain for poultry feed purposes irrespective of the outcome of the experiments you plan, nor are we in a position to participate in them. It has been our consistent policy to refuse to acquiesce in the use of moldy material in poultry feed in connection with salvage operations under the seizure section of the Act as well as under its import provisions. This policy is based upon the consensus of opinion among the authorities in the field of Veterinary Medicine who cannot assure us that the feeding of moldy material to poultry would be free of any possibility of adversely affecting the health of the birds. The outcome of any brief tests using some part of the 40,000 bushels involved here would not alter the applicability of our policy based on the consensus above. We have no disposition to close the door to the consideration of any proposals you may wish to make for some other use of this material which will in no way jeopardize public interests. \* \* \* Although there is no provision for an appeal under the import regulations of the Act, you are of course welcome to call at the Administration at any time for a discussion of your problem in connection with the proper disposal of this grain, having in mind the time limit prescribed by the order above."



[Scientific Testimony]

8. At the hearing in court the respective parties submitted interesting scientific testimony with respect to the suitability of the dried out grain for use as poultry feed. It was not controverted that the water damaged grain before being dried out was unsuitable for either human or animal food. Dr. Briggs, an expert poultry nutritionist at the University of Maryland testified to the results of experiments over a period of three weeks on chickens and baby chicks to which portions of the dried wheat had been fed. He said the chickens had thrived on the wheat which was mixed with other food, and expressed his opinion that it could be safely used generally for poultry food. Dr. J. H. Brown, Assistant Professor of Bacteriology at the Johns Hopkins University, an expert in his field, after giving extended testimony upon the general subject expressed the opinion that any danger to the poultry from the use of the dried wheat would be "remote." On the other hand, witnesses for the respondents, and particularly Dr. Elliott, Assistant Commissioner of Food and Drugs, also an expert upon the subject, after likewise detailed testimony expressed the opinion that the danger was more than remote. The practical viewpoint upon the subject was expressed by the witness Rieck, extensively engaged in poultry farming on the Eastern Shore of Maryland. He said that in his business he would not take the chance of loss and damage to growing chickens by the use of such damaged wheat, as the saving in cost for the food would not justify the risk of damage that might occur.

The scientific testimony was to the effect that not all moldy material was necessarily injurious to health. As for instance, the drug penicillin is itself a mold. Various articles of cheese are to some extent decomposed or moldy and are yet edible. But the particular contention of the respondents is that this particular damaged wheat contained a certain amount of aspergillus mold which is generally recognized by standard authorities to be damaging to chickens if the spores are inhaled. Dr. Brown thought it quite unlikely that there would be any such inhalation in the ordinary way in which the wheat mixed with other articles is fed to poultry; but experts for the respondents were of a contrary opinion.

[Question Involved]

On these facts the plaintiff contends that the administrative action was arbitrary and

capricious and should be enjoined. Consideration of this contention must be related to the particular situation giving rise to the controversy. If the order of the Collector for exportation or destruction was not within the grant of statutory power it should of course be enjoined, even though the statute does not provide for judicial review. *Waite v. Macy*, 246 U. S. 606; *Hannegan, Postmaster General, v Esquire*, U. S. Sp. Ct. Feb. 4, 1946. By Section 381 the Collector of Customs was authorized to refuse admission if the article was "adulterated." By Section 342 "a food shall be deemed to be adulterated—(3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food." We may put aside in this case the words filthy and putrid, but it is the contention of the government that the damaged wheat was decomposed and otherwise unfit for food. There was substantial evidence, and indeed it is not disputed by the plaintiff, that there was some decomposition in the wet wheat and to some extent at least it was fermented and moldy. The evidence is in conflict as to the extent of this fermentation and also in conflict as to whether the drying of the grain had arrested or merely retarded the process of fermentation. The ultimate question here is, I think, whether the decomposition was so extensive as to render the grain unfit for food. *Andersen v. United States*, 284 F. 542, 544; *United States v. 200 Cases of Catsup*, 211 F. 780.

And it is important here to distinguish between the condition of the grain when first offered for importation, and its condition after it had been dried. And it is also very important in this connection to note that there is really no controversy between the parties whether the wet grain before the drying was unfit for food of any kind, animal or human. In its original wet condition it was practically conceded that it was so unfit for any kind of food. The controversy as to its fitness for food is thus limited to the question as to whether after being dried it was fit for poultry feed. And here again on the evidence in the case taken in court the expert testimony was fairly evenly balanced. In my opinion, therefore, it cannot be said that the determination of the Food Administrator is not supported by substantial evidence. The plaintiff's particular contention to the contrary is that the decision of the Administrator was based on only a so-called organoleptic test, that is, by appearance, taste, texture, solubility,



viscosity and color. See *Knapp v. Calloway* (D. C. N. Y.) 52 F. 2d 467, 477. It may be noted, however, that subsequently and in preparation for trial of the case in court, the Food Administrator had expert bacteriological examinations made and submitted evidence therefrom tending to support his decision based on the previous organoleptic tests.

[*Power of Congress Over Imports*]

It is also very important in this case to note that the administrative action was taken in the field of *importation* in which the power of Congress is *exclusive and absolute*. *Buttfield v. Stranahan*, 192 U. S. 470, 493. The rights of the importer are, therefore, only those given in the Act of Congress in this case, 21 U. S. C. A., s. 381. And it will be noted that the statute itself deals only with the condition of the article when first offered for importation and its admission or rejection is to be determined by the Collector of Customs on the basis of advice from the Federal Security Administrator whether the samples show that the article offered for import is adulterated. In this case the Administrator did advise the Collector that the article was adulterated (within the meaning of the Act) and it is therefore clear enough that the Collector was authorized to refuse admission to the wheat in its originally tendered condition.

[*Contentions of Plaintiff*]

The plaintiff does not contend to the contrary but bases its present position on subsection (b) of Section 381 and on a regulation (2.309) providing under some circumstances for the reconditioning of the article offered for import in order to bring it within compliance with the Act, or to take such action as may be necessary to render it not a food product. Section 381 (b) provides that the Secretary of the Treasury may deliver the article to the consignee "pending examination and decision in the matter on execution of a bond." Section 2.309 of the regulations provides that the owner may request the Food Administrator in writing to permit the relabeling or other act with respect to the article necessary to bring it into compliance with the provisions of the Act or to render it not a food, and "such request shall propose the labeling to be used and any other act to be done for such purpose, and shall specify the time and place at which such proposed labeling or other act is to be done."

As we have seen, the Secretary, acting through the Collector, did permit delivery of the grain to the owner before passing his final order of December 11, 1945; but this was only for the limited purpose of drying the grain to prevent further spoilage. And thereafter the owner did not formally request permission to do anything with the grain (except dry it) to render it not a food. Instead thereof what the owner did request was permission to sell the dried grain as poultry feed. And this the Administrator refused to permit because in his expert opinion, based on generally accepted standards and information, it would not be safe for poultry growers to use even the dried grain for chicken feed. It is this action of the Food Administrator that is here attacked as arbitrary and capricious. As I have said, the scientific question presented is a nicely balanced one not free from doubt, but I conclude that the decision of the Food Administrator was not arbitrary or capricious. The plaintiff contends that it should be regarded as arbitrary and capricious because on the evidence injurious effects in poultry raising from the use of this damaged grain are not certain but only possible or conjectural. But I cannot accept this view as established by the preponderance of the evidence, and in any event it is my opinion that the decision of the Food Administrator on the basis of present scientific knowledge on the subject was not arbitrary or capricious.

Plaintiff also contends that under the evidence the Administrator did not accord him a fair hearing on this question. As heretofore stated, we are dealing with a subject matter of importation into the United States of articles where the power of Congress is absolute and the rights accorded the importer are only those given by the statute. The statute (s. 381) accords a hearing only after notice to the importer with respect to the samples taken from the bulk of the commodity to determine whether it is properly importable. At the hearing upon notice the only right accorded to the importer is "to introduce testimony." Presumably this testimony should be relevant to whether the samples are fairly illustrative of the bulk product, and if so whether the bulk product is properly importable. In the particular case the notice was duly given and the opportunity was afforded the importer to introduce testimony at the appointed time and place. Apparently the right was waived because it was practic-



ally conceded that the samples were fairly taken and the bulk product in its then condition was not importable under the Act. The plaintiff's complaint here is not lack of a fair hearing with regard to the samples of the wet grain but to the refusal of the Food Administrator to give a further hearing with respect to the availability of the dried grain for use of poultry feed. The statute does not provide for such a further hearing. Indeed the provision of the regulation referred to is not expressly provided for in the statute itself; but it is in the nature of an act of grace to the importer to recondition the article so that it will not be violative of the Act as a food product but may be used for other proper purposes not inconsistent with the Act, and thus possibly avoid unnecessary monetary loss.

[Judicial Review]

It is also to be noted that the statute does not provide for judicial review. In this respect the procedure under Section 381 is quite different from that taken under other sections of the Food and Drug Act of 1938 relating to domestic commerce, where proceedings for condemnation require judicial procedure. And Section 381 as it now stands is an amendment of the prior Act of 1906 (21 U. S. C. A., s. 14) in relation to importations, which also required judicial procedure for condemnation. See *Ambruster v. Mellon* (C. A. D. C.) 41 F. 2d 430, where it was held, under the earlier Act, that the action of the Secretary of the Treasury in admitting a certain importation was not subject to judicial review unless capricious or arbitrary. While there is no recorded case

of an attack on the Secretary's action under the new Act, it is clear that in the present case the statute makes no provision for judicial review and creates no personal federal rights as the basis for judicial review, so long as the Secretary acted within the scope of his authority under the Act. See *Stark v. Wickard*, 321 U. S. 288.

[Conclusion]

We must also bear in mind that the case does not present a question of confiscation by the government of a property right. Indeed the order here sought to be enjoined is merely in the alternative, that is, for exportation or destruction within three months. That period has now passed, but it was understood at the hearing here that the damaged wheat would not be destroyed pending decision of this case. And it appeared further in the evidence that the Administrator was still willing to consider any reasonable proposal from the importer to allow importation of the wheat if effective measures could be taken to use it for purposes other than food. It appears that the importer had an offer for the purchase of the remainder of the dried wheat (about 32,000 bushels) at the price of \$1.40 per bushel for use as poultry feed, and also another provisional offer for the wheat at \$1.00 per bushel for use for purposes other than a food product.

On the whole case I conclude that the complaint must be dismissed with taxable court costs allowed to the defendants. Counsel may present the appropriate order in due course.

---

**UNITED STATES v. 88 CASES, MORE OR LESS, EACH  
CONTAINING 24-6 $\frac{3}{4}$  FLUID OUNCE BOTTLES OF  
AN ARTICLE LABELED IN PART "BIRELEY'S  
ORANGE BEVERAGE." BIRELEY'S  
INC., CLAIMANT**

United States District Court for the District of New Jersey. Civil No. 4711.  
September 11, 1946. 5 F. R. D. 503.

In a seizure proceeding, a motion was made by the Government to vacate a notice of the taking of the oral deposition of the Commissioner of Food and Drugs or of such other employee of the Government as he might designate. In interpreting Section 304 (b), the court was required to look to the entire statute and not to the single clause in the section "and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty."

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.



The courts, including the Supreme Court, have expressed the view that in cases of forfeiture of articles seized on land for violation of Federal statutes, the district courts proceed as courts of common law; except as to filing the libel and obtaining jurisdiction, admiralty procedure does not apply; a forfeiture proceeding, after such preliminaries, takes the character of a law action and is governed by the Federal Rules of Civil Procedure.

Section 304 (b), Federal Food, Drug, and Cosmetic Act.

After an examination of the libel of information, it was held that discovery was not needed to inform the claimant as to what the Government alleged; and that what was sought by an examination of the Government's chemists doubtless consisted of expert testimony or opinions on the part of the chemists who had made analyses of samples of the seized commodity, which was not the kind of evidence that the Government should be required to disclose, under the Federal Rules of Civil Procedure, in seizure proceedings.

Sections 304 (b), 304 (c), Federal Food, Drug, and Cosmetic Act.

Edgar H. Rossbach, U. S. Attorney, Charles D. Hyman, Assistant U. S. Attorney (Lawrence E. Bobker, Attorney, Federal Security Agency, of counsel), for libelant.

Starr, Summerill & Lloyd (Lester E. Waterbury and Mark C. Candee, of counsel), for claimant.

### **On Motion to Vacate Claimant's Notice To Examine Party**

[*Nature of Proceeding*]

MADDEN, District Judge: This is a motion by the United States of America, as libelant, to vacate a notice of the taking of oral deposition of Dr. Paul B. Dunbar, Commissioner of Food and Drugs—or such other officer, agent, employee or representative as he may designate—pursuant to Rules 26, 28, 30, 32 and 37 of the Rules of Civil Procedure.

This is a proceeding under the Federal Food, Drug, and Cosmetic Act of June 25, 1938, (21 U. S. C. 301 *et seq.*) seizure having been made under Section 334, because the subject matter, namely, an uncarbonated beverage is alleged to have been adulterated and misbranded.

[*Contentions of the Government*]

The motion by the Government is made upon two grounds. First: That the proceeding being upon a libel is a proceeding in admiralty and is therefore not governed by the Federal Rules of Civil Procedure, 28 U. S. C. A. following Section 723 (c), pursuant to which the notice of the taking of depositions was given, and, Second: That if the Federal Rules of Civil Procedure do apply, discovery would not be appropriate in this particular case.

It therefore follows that a study must be made to determine the first question, and if this is decided in favor of the libelant, there is no need of passing to the second question.

[*Particular Statutory Provisions Involved*]

The particular section of the Food, Drug, and Cosmetic Act (21 U. S. C. A. 301 *et seq.*) namely, Section 334 (b) provides among other things:

“The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury.”

Since the notice sought to be dismissed is brought under the Federal Rules of Civil Procedure, it becomes necessary to determine whether such rules apply. Rule 81 says, (1) These rules do not apply to proceedings in admiralty. Paragraph 2 of Rule 81 says:

“In the following proceedings appeals are governed by these rules, but they are not applicable otherwise than on appeal except to the extent that the practice in such proceedings is not set forth in Statutes of the United States and has heretofore conformed to the practice in actions at law or suits in equity; admission to citizenship, habeas corpus, quo warrant and forfeiture of property for violation of a statute of the United States.”

The footnote concerning this provision of the Rule adds this:

“For examples of statutes which are preserved by paragraph (2) see—Title 21, par. 14 (Pure Food and Drug Act—Condemnation of adulterated or misbranded



Food; procedure)."

So that if these statutes and rules were all that the court had to guide it in its disposition of the motion, its way would seem clear. However, the rules were adopted in 1939 and we must look to the decisions since their adoption and even prior thereto for further enlightenment.

In interpreting the statute in question, we must look to the entire statute and not to the single phrase "and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty."

[Cases Compared]

In 1932, Justice Butler, speaking for the Supreme Court in the matter of *D. Ginsberg & Sons, Inc. v. Popkin* (285 U. S. 204) said:

"General language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment. *U. S. v. Chase*, 135 U. S. 255, 260. Specific terms prevail over the general in the same or another statute which otherwise might be controlling. *Kepner v. U. S.*, 195 U. S. 100, 125. *In re Hassenbusch*, 108 Fed. 38. *United States v. Peters*, 166 Fed. 613, 615. The construction contended for would violate the cardinal rule that, if possible, effect shall be given to every clause and part of a statute. *Market Co. v. Hoffman*, 101 U. S. 112, 115. *Ex parte Public National Bank*, 278 U. S. 101, 104."

And in *Jones v. York County*, 47 Fed. 2d 837, Judge Gardner, speaking for the Eighth Circuit, said:

"It is a recognized rule of construction or interpretation that the legislative intent is to be deduced from a view of the whole and every part of the statute taken and compared together, and, if possible, this act should be so construed as to render it a consistent and harmonious whole, and that construction should be favored which will render every provision operative, rather than one which would make some of its provisions idle or nugatory."

In 1912, the Supreme Court had before it, the question of interpreting this very phrase in the then Food and Drug Act, in the matter of *443 Cans of Frozen Egg Products v. United States* (226 U. S. 180) and there Mr. Justice Day said:

"A statute, practically the same, with some slight changes, was embodied in par. 563 of the Revised Statutes, subdivision 8, giving the District Courts jurisdiction 'of

all civil causes of admiralty and maritime jurisdiction . . . and of all seizures on land and on waters not within admiralty and maritime jurisdiction,' the subdivision mentioned omitting the provision found in the section of the Judiciary Act of 1789 to which we have referred as to seizures 'within their respective districts,' and including case of 'seizures on land and on waters not within admiralty and maritime jurisdiction.' Under this statute it has been uniformly held that the District Court as to seizures on land proceeds as a court of common law with trial by jury and not as a court of admiralty."

In the present matter the seizure is a seizure on land and well recognizable as such.

[Decisions in Point]

The counsel for the government strenuously urges for consideration the case of *United States v. 720 Bottles*, 3 Federal Rules Decisions 466. This case is identical with the present case and there District Judge Byers held that the admiralty rules applied and sustained the government's motion.

However, the Second Circuit has felt otherwise, in other cases, for in the matter of *Eureka Productions Inc. v. Mulligan* (108 Fed. 2d 760) Judge Patterson said:

"(1, 2) Since the seizure took place on land, the suit by the United States to condemn the film for violation of customs law was an action at law rather than a suit in admiralty. In the case of seizures on land, suit for condemnation of the thing seized, though brought in the form of a libel of information in admiralty and governed to some extent by Admiralty Rule 22, 28 U. S. C. A. following section 723, is inevitably an action at law. *The Sarah*, 8 Wheat, 391, 5 L. Ed. 644; *Morris Cotton*, 8 Wall. 507, 19 L. Ed. 481; *Confiscation Cases*, 20 Wall. 92, 22 L. Ed. 320. The District Court in such cases proceeds as a court of common law on the equivalent of an information *in rem*, its jurisdiction being like that of the old Court of Exchequer in seizures for forfeiture of property to the Crown. 1 Kent's Commentaries, page 375; 3 Blackstone's Commentaries, page 261.

"The resemblance to a suit in admiralty does not go beyond the process and the initial pleadings, even in cases where the statute providing for confiscation directs that the proceedings shall conform to proceedings in admiralty as near as may be. *In re Graham*, 10 Wall. 541, 19 L. Ed. 981; *443 Cans of Frozen Egg Product v. United States*, 226 U. S. 172, 33 S. Ct. 50, 57 L. Ed. 174. It follows that the decree of condemnation and writ of destruction remained in full force, notwithstanding the ap-



peal, and justified the marshal in destroying the film."

And the Supreme Court reiterated its position as stated in the *443 Cans of Frozen Egg Product* case as recently as 1943 when our late Chief Justice Stone, in the case of *C. J. Hendry v. Moore* (318 U. S. 133 at page 153) said:

"The Court has never held or said that the admiralty jurisdiction in a forfeiture case is exclusive, and it has repeatedly declared that, in cases of forfeiture of articles seized on land for violation of federal statutes, the district courts proceed as courts of common law according to the course of the Exchequer on information *in rem* with trial by jury."

Likewise, in the Sixth Circuit, June, 1943, Judge Martin, in the case of *U. S. v. 935 Cases, Tomato Puree* (136 Fed. 2d 525, 526) said:

"Recognition that proceedings under the provisions of Section 10 of the Pure Food Act of June 30, 1906, 34 Stat. 768, 21 U. S. C. A. Par. 14, where this procedure was originally prescribed by Congress, shall be by libel *in rem* and shall conform as nearly as may be to proceedings in admiralty was given by the Supreme Court in *Four Hundred and Forty-Three Cans of Frozen Egg Product v. United States*, 226 U. S. 172, 178, 182, 183, 33 S. Ct. 50, 57 L. Ed. 174. *It was commented there that the provision of the Act giving to either party the right to demand a jury trial of issues of fact was inserted with a view to removing any question as to the constitutionality of the Act, and that it was not intended to liken the proceedings to those in admiralty beyond the seizure of the property by process in rem.*"

And as recently as December, 1945, the Fifth Circuit passed on the matter in the case of *Reynal v. United States* (153 Fed. 2d 929) and Judge Hutcheson said:

"We agree with the government that, except as to filing the libel and obtaining jurisdiction, admiralty procedure does not apply. A forfeiture proceeding after these preliminaries takes the character of a law action, and under Rule 81 (a), (2), Federal Rules of Civil Procedure, 28 U. S. C. A., following section 723c, is now governed by those rules. Therefore, appellant may not invoke Admiralty Rule 39 for setting aside a default."

[Federal Rules of Civil Procedure Apply]

So that I must overlook the opinion by District Judge Byers in the matter of *United States v. 720 Bottles, supra*, even though it is directly on point and hold that the present proceeding, while commencing as a libel

under the Admiralty Rules, nevertheless, is a seizure upon land and at this stage of the proceedings the Federal Rules of Civil Procedure apply.

[Discovery Not Appropriate]

It therefore becomes necessary to consider the second grounds urged in support of the government's motion, namely, is discovery appropriate in this case?

The libel filed by the government is, for the purpose of this motion, full and complete in informing the claimant how the seized article is adulterated and misbranded.

Paragraph III of the libel alleges:

"—that the said article is adulterated—in that yellow coal tar dyes have been mixed therewith so as to make the said food look like a product composed entirely or in large part a fresh orange juice and thus better and of greater value than it is."

Paragraph IV alleges:

"—that it consists of a mixture of a small quantity of concentrated citrus juice or juices and water, to which have been added additional water, in excess of that contained in the fresh juices from which the concentrates were made, sugar, lactic acid and orange oil, which substances so added to the said food increases the bulk thereof and gives it the taste and odor of an orange juice or of a beverage containing a large quantity of an orange juice, thereby making the said food appear better and of greater value than it is."

It is therefore quite apparent that discovery is not needed to inform the claimant what the government alleges and it is likewise apparent that what is sought by an examination of the government's chemists doubtless consists of expert testimony or opinions on the part of the chemists who have made analysis of samples of the commodity which has been seized. Therefore, is discovery appropriate?

In the case of *Lewis, et al., v. United Air Line Transportation Corporation, et al.*, D. C. W. D. Penna. (32 Fed. Supp. 21) Judge McVicar said:

"To permit a party by deposition to examine an expert of the opposite party before trial, to whom the latter has obligated himself to pay a considerable sum of money, would be equivalent to taking another's property without making any compensation therefor. To permit parties to examine the expert witnesses of the other party in land condemnation and patent actions, where the evidence nearly



all comes from expert witnesses, would cause confusion and probably would violate that provision of Rule 1 which provides that the rules 'shall be construed to secure the just, speedy, and inexpensive determination of every action'."

And in *Boynton v. R. J. Reynolds Tobacco Co.*, (36 Fed. Supp. 593) D. C. Mass., Judge McLellan, speaking of examining expert witnesses said:

"(3) But there are cases where the tender of compensation should have no such effect. An expert employed by one of the parties ought not to be compelled to furnish expert testimony to the other just because the latter offers him compensation. It is his privilege, if not his duty, to refuse compensation from one of the parties when he has already accepted employment from the other, and such refusal ought not of itself to result in his being ordered to testify.

"(4) To recapitulate, the court has the power, in the exercise of its discretion, to allow this motion or to deny it. Such is the view indicated in *Barrus v. Phaneuf*, *supra*. And to me it seems that as a discretionary matter, under the circumstances of the instant case, the defendant should not be permitted to obtain from an expert witness an opinion for which the plaintiff has to pay. Nothing here said is intended as an intimation that if the defendant had tendered a fee to the witness, who had declined it, any different result would have been reached."

I therefore feel that an analysis and the conclusion based thereon constitute the kind of evidence that the government should not be required to disclose to the claimant in this type of litigation.

The motion to vacate claimant's notice to examine party is, according to the views expressed herein, granted.

---

## UNITED STATES v. 300 CANS, ETC., OF BLACK RASPBERRIES, ET AL.

United States District Court for the Northern Division of Ohio, Eastern Division. Civil No. 24371. December 10, 1946. 7 F. R. D. 36.

In a seizure proceeding, the claimant filed a motion to allow it to take samples for the purpose of making tests. Since there was no opposition thereto and since Section 304 (c) so provided, an order would be entered accordingly.

Section 304 (c), Federal Food, Drug, and Cosmetic Act.

On motion for an order requiring the Government to disclose its records with reference to its tests and analyses, it was held that the action was a civil proceeding *in rem*, to which, following the issuance of process, the Federal Rules of Civil Procedure are applicable.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The application of the admiralty procedure to this type of proceeding has been limited by the Supreme Court to the seizure of the property by process *in rem*; and Rule 81 (a) (2) of the Federal Rules of Civil Procedure makes such Rules as are applicable to law cases also applicable to proceedings in forfeiture after the issuance of process.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The fact that fresh fruits and vegetables rapidly deteriorate furnishes ground for believing that Congress, in Section 304 (c), intended to guarantee an opportunity to the party in interest to secure samples and analyses. It does not follow that samples and analyses of other articles may not be had in proper circumstances.

Sections 304 (a), 304 (b), 304 (c), Federal Food, Drug, and Cosmetic Act.

Don C. Miller, Cleveland, Ohio, for the United States.

Harley J. McNeal, Cleveland, Ohio, for parties in interest.



*[Action in Forfeiture]*

JONES, District Judge: This is an action in forfeiture under the Federal Food, Drug, and Cosmetic Act against 300 cans of black raspberries.

*[Motion To Take Samples]*

The claimant, Sunshine Packing Corporation, has filed a motion to allow it to take samples for the purpose of making tests. There being no opposition to this part of the motion and the law so providing (Sec. 334 (c), Title 21, U. S. C.), an order may be entered accordingly.

*[Motion To Require Government To Disclose Records]*

The claimant further moves for an order requiring the Government to disclose its records with reference to its tests and analyses. This part of the motion is opposed. These are civil proceedings *in rem* to which, following the issuance of process, the Rules of Civil Procedure are applicable.

Section 334 (b), Title 21, U. S. C. provides:

"\* \* the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; \* \*."

*[Admiralty Procedure Limited by Supreme Court]*

The application of the admiralty procedure to this type of proceeding has been limited by the Supreme Court to the seizure of the property by process *in rem*.

"We do not think it was intended to liken the proceedings to those in admiralty beyond the seizure of the property by process *in rem*, then giving the case the character of a law action." (*Four Hundred and Forty-three cans of Frozen Egg Product v. U. S.*, 226 U. S. 183; *U. S. v. 935 Cases Tomato Puree*, 136 F. (2d) 523, certiorari denied 320 U. S. 778.)

Rule 81 (a) (2) of the Rules of Civil Procedure provides that the rules

"are not applicable otherwise than on appeal *except* to the extent that the practice in such proceedings is not set forth in statutes of the United States and has heretofore conformed to the practice in actions *at law* or suits in equity: \* \*."

The Supreme Court having held that a suit in forfeiture has the character of a law action and having limited the application of the statute providing for the admiralty procedure to the process *in rem*, it seems that Rule 81 (a) (2) makes the Civil Rules which are applicable to law cases also applicable to proceedings in forfeiture after the issuance of process.

The Rules of Civil Procedure are very liberal in allowing the inspection of documents which are not privileged. (Rule 34.) There is no showing that these records are privileged nor can there be any doubt that these records are material evidence.

The motion to inspect will be granted. Enter order accordingly.

*[Supplemental Opinion]*

Because of the serious insistence of the Government that the Court wrongly concluded to grant the consignor's motion of October 16, 1946 (memorandum filed December 10, 1946), the matter has been re-examined in the light of supplemental briefs.

Reconsideration, however, has led to the same result and the former ruling will be adhered to with some further elaboration of the basis for the conclusion there reached.

The Government relies upon the strict exclusiveness of the language used in Section 334 (c), Title 21, U. S. C. A., and I assume, would contend that there is no modification in respect of samples for analysis provided by Section 372 (b) of the same Title. I suppose it could be argued that even Section 372 (b) does not extend the availability of analyses of samples made by the Administrator of articles seized.

However, in view of the trend of The Rules of Civil Procedure which previously I have held to be applicable to proceedings of this character, and the liberal construction to be given the forfeiture statute, as well as rules of Civil Procedure such as Rules 26, 33 and 34, recently interpreted by the Supreme Court, I think "the dark veil of secrecy over pertinent facts" ought not longer to stand where, as here, the party in interest is brought into potentially serious collision with the Government and his property summarily seized and held for condemnation.

The fact that fresh fruits and vegetables rapidly deteriorate or decay furnishes ground for believing that the Congress intended to guarantee an opportunity to the party in interest to secure samples and analyses. It does not follow, however, that samples and analyses of other articles may not be had in proper circumstances.

The opinion in *Hickman v. Taylor*, decided by the Supreme Court January 13, 1947, would seem to have extended the sweep of the Rules above-mentioned be-



yond the limitations of this Court's ruling on interrogatories in *United States v. Tomato Puree*, Civil No. 21218, March 22, 1944.

In such circumstances, I find neither prejudice resulting, nor statutory limitations

violated by requiring response to the motion.

An order may be entered accordingly with exceptions to the Government.

## MANNING v. UNITED STATES

United States Circuit Court of Appeals for the Fifth Circuit. No. 11848.

May 28, 1947. 161 F. 2d 827.

A probation officer filed a complaint charging that the defendant, who had been placed on probation after having been convicted of violating the Act, had violated the conditions of his probation. A proceeding for revocation of probation is not one of formal procedure either with respect to notice or specification of charges or a trial upon charges.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

A probationer may not have his probation revoked unless it is made to appear that he has failed to comply with the terms and conditions of his probation.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Action of a trial judge in revoking probation is an exercise of broad discretionary power, and on appeal the question is simply whether there has been an abuse of discretion. There was abundant evidence indicating that the defendant had been prescribing and selling worthless medicines.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Proof sufficient to support a criminal conviction is not required to support a judge's discretionary order revoking probation. The record disclosed no abuse of discretion by the trial judge but a sound exercise of judicial discretion.

Sections 301 (a), 303 (a), Federal Food, Drug, and Cosmetic Act.

Before HUTCHESON, McCORD, and WALLER, Circuit Judges.

### *[Violation of Act by Appellant]*

McCORD, Circuit Judge: On October 18, 1945, on plea of guilty, Donald R. Manning was convicted on eight counts of an information charging him with unlawfully introducing in interstate commerce a number of packages containing drugs which had been misbranded, all in violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 352 (a). Manning was sentenced to thirty days imprisonment under count one, and on the other counts was placed on probation for a period of three years.

### *[Violation of Conditions of Probation]*

On November 13, 1946, the probation officer filed a complaint charging that Manning had violated the conditions of his probation. The matter came up for hearing on November 15, 1946, and Manning moved

for a more definite and formal complaint setting out the charges against him. The motion was denied, but there was filed a statement which recited: "Violations of Conditions of Probation: 1. Practicing medicine without a license during period from May 1, 1946, to August 31, 1946. 2. On or about May 9, 1946, used the mails to defraud Charles Ebel of Box 117, Cherokee, Ala. 3. On or about August 26, 1946, used the mails to defraud M. T. Hanson, Repton, Ala. 4. On or about August 26, 1946, used the mails to defraud Olive Harold of Box 369, Bay Minette, Ala." The hearing was continued until November 22, 1946, and was then conducted before the district judge that had originally placed Manning on probation. Testimony for and against Manning was received, and at the conclusion of the hearing the district judge revoked Mann-



ing's probation,<sup>1</sup> fined him \$750.00, and committed him to the custody of the Attorney General for a period of one year. From the order revoking the probation, Manning has appealed.

[*Contentions of Appellant*]

Appellant contends that he was entitled to have in advance a list of adverse witnesses and a more particular specification of the charges against him than was furnished; that there were no conditions of probation pronounced at the time he was placed on probation; and that the evidence at the hearing was not sufficient to justify revocation of probation on either of the theories: (1) that he was using the mails to defraud, (2) that he was practicing medicine without a license, or (3) that he was not leading an honest life as required by the alleged conditions of probation.

[*Proceeding Not One of Formal Procedure*]

As to appellant's allegations that the complaint against him was not specific enough, it is sufficient to say that a proceeding for revocation of probation is not one of formal procedure "either with respect to notice or specification of charges or a trial upon charges. The question is simply whether there has been an abuse of discretion and is to be determined in accordance with familiar principles governing the exercise of judicial discretion." *Burns v. United States*, 287 U. S. 216; *Escoe v.*

*Zerbst*, 295 U. S. 490; *Dillingham v. United States*, 76 F. 2d 35.

[*Conditions of Probation Not Included in Judgment*]

A probationer may not have his probation revoked unless it is made to appear that he has failed to comply with the terms and conditions of his probation. *Mankowski v. United States*, 148 F. 2d 143, 144. Appellant accordingly asserts that no terms or conditions of probation were included in the judgment placing him on probation. This contention is without basis or merit. Since September 21, 1939, there has been in the District Court of the Northern District of Alabama a standing order imposing general conditions of probation.<sup>2</sup> Not only did this order apply to Manning's case, but the conditions in the order were specifically called to his attention in a written statement, of which he received a copy, and for which he gave his receipt in writing.<sup>3</sup>

[*Revocation of Probation Discretionary*]

There is no merit in appellant's contention that the evidence was not sufficient to justify revocation of his probation. Action of a trial judge in revoking probation is an exercise of broad discretionary power, and on appeal the question is simply whether there has been an abuse of discretion. *Burns v. United States*, 287 U. S. 216; *Pritchett v. United States*, 67 F. 2d 244. There is abundant evidence in this record from which the trial judge could, and did,

<sup>1</sup> In revoking the probation, the trial judge stated: "As I see the evidence in this case, I think this man is engaged in a business which constitutes a fraud on the general public. I think he is out there practicing medicine, and I think it should be stopped. And I think he is selling these alleged herb medicines to ignorant people \* \* \* and he is liable to cause them to die from want of proper medical care. \* \* \* It is really based on three things. In the first place, I think he is practicing medicine without a license, and I think he is making a diagnosis of ailments, and, as I said, preparing medicine and representing it will cure. In addition to that, he has signs advertising to Negroes and very ignorant people. I think he is holding himself out to them as a doctor, \* \* \* he is using a stethoscope, and I think under all the facts in this case he is practicing medicine. As I say, I think it is a fraud on the public which should not be tolerated. They were after him, according to the records that have been furnished me from the Probation Department, about practicing in Georgia without a license. Under his own statement, he was practicing in Georgia without a license, and he has come over here and is making a lot of money out of it. I am revoking his probation, first, on the theory that he is practicing medi-

cine without a license. Second, on the theory he is using the mails to defraud. And, third, on the theory he is not leading an honest life as required by the conditions of probation. In other words, I think he is in a dishonest business and I think it is a fraud on the general public. \* \* \* "

<sup>2</sup> This standing order on probation conditions was not included by appellant in his record on appeal, but this court directed that it be sent up. This order provides, among other things, that a probationer must: "6. Conduct himself or herself honorably, work diligently at a lawful occupation and support his or her dependents, if any, to the best of his or her ability. 9. Not violate any law; local, state or national."

<sup>3</sup> The written notice of conditions which Manning received advised him of the general conditions of probation: "The general conditions of probation are as follows: (a) Refrain from the violation of any state and federal penal laws. (b) Live a clean, honest, and temperate life. \* \* \* " Manning admitted that he had received the copy of the conditions of probation. The Court: "I want to ask you if you signed those conditions at the time I placed you on probation in this case?" Manning: "Yes, sir, I did."



conclude that Manning, in the conduct of his herb business, was holding himself out to ignorant people as a doctor; that he was purporting to diagnose ailments and was prescribing medicines for their cure; that the medicines which he prescribed and sold by mail were not beneficial, but were, in many instances, absolutely worthless and harmful to the patient; and that Manning was not leading an honest life, but was perpetrating a fraud on the public.

It may be, as appellant contends, that the evidence on the probation revocation hearing would not be sufficient to support a conviction under federal laws for using the mails to defraud or under Alabama law for practicing medicine without a license. But proof sufficient to support a criminal conviction is not required to support a judge's discretionary order revoking probation. A judge in such proceeding need

not have evidence that would establish beyond a reasonable doubt guilt of criminal offenses. All that is required is that the evidence and facts be such as to reasonably satisfy the judge that the conduct of the probationer has not been as good as required by the conditions of probation. *Campbell v. Aderhold*, 36 F. 2d 366; *United States v. Hanson*, 49 F. Supp. 355.

[*Order Revoking Probation Upheld*]

Manning was given a full, fair, and comprehensive hearing before the trial judge. The record, instead of showing abuse of discretion on the part of the trial judge, discloses a sound exercise of judicial discretion and fully supports the order revoking appellant's probation.

The judgment is

AFFIRMED.

---

**COOK CHOCOLATE COMPANY v. WATSON B. MILLER,  
THE FEDERAL SECURITY ADMINISTRATOR,  
AND TOM C. CLARK, THE ATTORNEY  
GENERAL OF THE UNITED  
STATES**

United States District Court for the District of Columbia.

Civil Action 684-47. July 7, 1947. 72 F. Supp. 573.

Plaintiff, a manufacturer of sweet chocolate, sought to have the Federal Security Administrator hold a public hearing on the question of amending his regulation with respect to sweet chocolate to permit the addition of certain vitamins. The plaintiff's application stated that the Administrator had permitted vitamins to be added to certain cereals; that the British Ministry of food had announced that chocolate had been found to be the best medium for administering vitamin concentrates; and that the United States Army and Red Cross had ordered vitaminized chocolate on a large scale. Plaintiff asked for a public hearing, which was refused, and brought suit for a declaratory judgment. On motion to dismiss, it was held that if the allegations of the petition were true, the action of the Administrator was clearly arbitrary and not based on the statutory criterion.

Section 701 (e), Federal Food, Drug, and Cosmetic Act.

With respect to the plaintiff's right to a declaratory judgment as to whether its product was barred by the regulations, the question was governed by *Helco Products Co., Inc. v. McNutt*, 78 App. D. C. 71, and as to that, and as to the defendant Attorney General, the complaint should be dismissed.

Sections 301 (a), 304 (a), 305, 307, Federal Food, Drug, and Cosmetic Act.

JENNINGS BAILEY, District Judge: Section 371 (e) of the Federal Food, Drug, and Cosmetic Act provides that the Administrator, on his own initiative or upon an application of any interested industry or sub-

stantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by certain sections of the Act. The Act further



provides that after the public hearing the industry seeking a change in the regulation may appeal to the Court of Appeals from any order made by the Administrator based upon the evidence given at the public hearing.

*[Public Hearing Requested]*

In this case the plaintiff, who is a large manufacturer of sweet chocolates, has sought to have the Administrator have a public hearing to amend his regulation upon sweet chocolates so that certain vitamins may be added to the chocolates. The plaintiff manufacturing a sweet chocolate to which certain vitamins have been added, the whole being sold under the name of Vita Sert, stated in his application certain facts in support of his application that the Administrator had permitted vitamins to be added to certain cereals providing optional standards for vitamin enrichment in Farina, macaroni, wheat, flour, and corn meal; that the British Ministry of Food announced that chocolate had been found to be the best medium for administering vitamin concentrates; that the United States Army had ordered and utilized vitaminized chocolate on a large scale in its emergency ration; that the Red Cross had also used large quantities of it for undernourished persons abroad, and annexed to its application letters from eminent physicians and other authorities.

*[Nature of Proceeding]*

The Administrator refused to hold a public hearing, saying that no reasonable ground was shown for holding it. Thereupon, plaintiff brought this suit, seeking a declaratory judgment, and to direct the Administrator to hold a public hearing upon plaintiff's application, and that the court determine that the plaintiff's product Vita Sert does not violate the Cacao products regul-

ation established by the Federal Security Administrator.

*[Powers of the Administrator]*

The defendant, the Federal Security Administrator, has moved to dismiss the complaint on the ground that the court is without jurisdiction and that the complaint fails to state facts sufficient to constitute a cause of action. As to the question of jurisdiction he contends that the action of the Administrator is a discretionary one and that the court has no power to review it. However, if the foregoing allegations of the petition filed with the Administrator are true, the action of the latter is clearly arbitrary. His power to fix regulations is given whenever "in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers" and his holding that the plaintiff's application did not show reasonable grounds was not based upon this power but apparently upon some general authority not vested in him by the statute to define whether or not the addition of vitamins to chocolates to be used as a confection would be used by the public in sufficient quantities to justify a new regulation or an amendment to the existing regulation. See *Perkins v. Ely*, 307 U. S. 325.

*[Conclusion]*

So far then, as the action of the Administrator in denying plaintiff's application is concerned, the motion to dismiss the complaint will be overruled.

As to plaintiff's right to declaratory judgment as to whether or not its product Vita Sert is barred by the defendant's regulation, this question is governed by the case of *Helco Products Co., Inc. v. McNutt*, 78 App. D. C. 71. As to that and also as to the defendant, the Attorney General, the motion to dismiss will be sustained.



UNITED STATES OF AMERICA v. 74 CASES, MORE OR LESS, and 84 Cases, More or Less, Each Containing 24 Jars of an Article Labeled in part: (Jars) "Cobbs Pure Tropical Fruit Delicacies Plum Jelly \* \* \* Net Wt. 1 lb. \* \* \*"; and

113 Cases, More or Less, Each Containing 24 Jars of an Article Labeled in part: (Jars) "Cobbs Pure Tropical Fruit Delicacies Grape Jelly \* \* \* Net Wt. 1 lb." (F. D. C. No. 22668),

77 Cases, More or Less, Each Containing 24 Jars of an Article Labeled in part: (Jars) "Cobbs Pure Tropical Fruit Delicacies Plum Jelly \* \* \* Net Wt. 1 lb." (F. D. C. No. 22669),

22 Cases, More or Less, Each Containing 24 Jars of an Article Labeled in part: (Jars) "Cobbs Pure Tropical Fruit Delicacies Plum Jelly \* \* \* Net Wt. 1 lb." (F. D. C. No. 22670)

United States District Court for the District of Minnesota, Fourth Division.  
Civil No. 2417. September 24, 1947. 73 F. Supp. 1009.

In a seizure action, a concern to which the product had been sold by the manufacturer moved that it be permitted to file a cross-complaint against the seller alleging damages for breach of warranty in the sale of the product. The proceeding was one *in rem*; and the procedure must conform, as nearly as may be, to the admiralty rules.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The only question in the libel proceeding was whether the merchandise was misbranded, and in determining that issue the question of the ownership of the product was properly before the court.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The court could not assume jurisdiction of a claim by the buyer for breach of warranty against the seller; such issue was not within the jurisdiction of the court, but was a collateral common law proceeding *in personam*.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

The only jurisdiction the court had over the seller was with reference to the right of the Government to seize goods in which the seller claimed it had an interest, and the seller had appeared for that limited purpose and no other.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

There was no admiralty rule which would avail the petitioner; the attempt to ingraft on a so-called admiralty proceeding *in rem* a common law proceeding *in personam* was completely without the purview of Rule 56 of the Admiralty Rules.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The fact that the court had possession of the *res* did not permit it to determine any controversy other than the ownership of the property, the ultimate question of misbranding, and the right of the owners of the property if there was misbranding.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

Victor E. Anderson, U. S. Attorney, St. Paul, Minn., for libelant.

W. P. Berghuis, Minneapolis, Minn., for Gamble-Skogmo, Inc.

Messrs. Brazeau and Graves, Wisconsin Rapids, Wis., for Cobbs Fruit & Preserving Co.



NORDBYE, GUNNAR H., District Judge: This matter came before the Court on the motion of Gamble-Skogmo, Inc., for an order requiring the two claimants to the property involved in these proceedings to interplead so that all claims and causes of action between them may be fully tried and determined in this proceeding.

Mr. W. P. Berghuis, of Minneapolis, Minnesota, appeared in behalf of Gamble-Skogmo, Inc., in support of said motion; and Messrs. Brazeau and Graves, of Wisconsin Rapids, Wisconsin, appeared in behalf of Cobbs Fruit & Preserving Company in opposition thereto.

[*Damages for Breach of Warranty*]

The two claimants to the jelly seized in this proceeding are Cobbs Fruit & Preserving Company, hereinafter called the Cobbs Company, the manufacturer of the product, and Gamble-Skogmo, Inc., which contends that this property was sold to it and the title passed before the seizure. Answers have been filed by both of the claimants, and that issue of ownership is now before the Court on the pleadings filed. But Gamble-Skogmo, Inc., in the motion now presented, seeks an order whereby it will be permitted to file a cross-complaint against the Cobbs Company alleging damages for breach of warranty in the sale of the particular jelly which is the subject matter of this libel proceeding.

[*Conformity to Admiralty Rules*]

This is a proceeding *in rem*. The procedure shall conform as nearly as may be to the admiralty rules. But cases arising in admiralty are not particularly helpful, as was recognized by the Supreme Court in *443 Cans of Egg Product v. United States*, 226 U. S. 172, 183, when it made the following observations in a proceeding arising under the Pure Food Act:

"We do not think it was intended to liken the proceedings to those in admiralty beyond the seizure of the property by process *in rem*, then giving the case the character of a law action, with trial by jury if demanded and with the review already obtaining in actions at law."

The language in the present statute under the Pure Food and Drug Act with reference to the procedure to be followed is substantially the same as it was when the Supreme Court had the proceeding under the Pure Food Act in the *443 Cans of Egg Product* case.

[*Jurisdiction of Court*]

At the outset, it must be kept in mind that the only question in the present libel proceeding is whether the merchandise was misbranded in violation of the statutes of the United States, and in determining that question the ownership of the jelly is properly before the Court. It is conceded by the Cobbs Company that the issue of ownership as between the two claimants is a matter that may be litigated in the present proceeding. But that issue is only incidental to the proceeding by the Government to condemn the property. However, as to that issue, the Cobbs Company is willing to admit that title passed to Gamble-Skogmo, Inc., if that company presses that contention in this proceeding. But, obviously, this Court cannot assume jurisdiction of a claim by Gamble-Skogmo, Inc., for breach of warranty against the Cobbs Company. That issue is not within the jurisdiction of this Court. It is a collateral common law proceeding *in personam*. This is strictly a matter *in rem*. The Cobbs Company is a resident of Florida. It does not do any business in this State; it has no agent in this State; it has no representative herein upon whom service can be made so as to vest this Court with jurisdiction in the contemplated proceeding embraced within this petition. If this Court did make the order prayed for, and permitted petitioner to file a cross-complaint setting up this claim for breach of warranty, the Cobbs Company could refuse to respond, and any proceedings therein with reference to any personal judgment against the Cobbs Company growing out of a claim for breach of warranty would be utterly void. The only jurisdiction this Court has over the Cobbs Company is with reference to the right of the Government to seize goods in which it claims it has an interest, and it has appeared in this proceeding for that limited purpose and none other.

[*Issues Determinable by Court*]

In so far as the admiralty procedure may be appropriate, there is no admiralty rule which will avail this petitioner. It refers to Rule 56 of the Admiralty Rules, but the attempt to ingraft on a so-called admiralty proceeding *in rem* a common law proceeding *in personam* is completely without the purview of that rule. See *Eggleston v. Republic Steel Corp.*, (D. C. W. D. N. Y.) 47 F. Supp. 658. Nor will the fact that the Court has possession of the *res* permit it to determine any controversy other than the ownership of



the property, the ultimate question of misbranding, and the rights of the owners of the property under the statutes if there is misbranding. The claim for damages for breach of warranty does not affect the property seized, nor is that issue one that should be determined in order for the Court in a *rem* proceeding to adjust all of the rights of the parties in a single suit. The common law claim for damages for breach of warranty growing out of the sale of the merchandise seized and the Cobbs Com-

pany's defense thereto are foreign to any issues which this Court should determine in adjusting all of the rights of the parties in the *rem* proceeding. The determination of the question seems so elementary that to cite authorities in support of the foregoing should be unnecessary. Therefore,

It is ordered: That the motion of Gamble-Skogmo, Inc., be, and the same hereby is, in all things denied. An exception is allowed.

---

**UNITED STATES OF AMERICA v. 215 CASES, MORE OR LESS, Each Case Containing 24 Bottles of an Article Labeled in Part: (Bottles) "Michigan Brand Grade A Tomato Catsup Contents 14 oz. Avoir. \* \* \*"**

**UNITED STATES OF AMERICA v. 902 CASES, MORE OR LESS, Each Case Containing 24 Bottles of an Article Labeled in Part: (Bottles) "Michigan Brand Grade A Tomato Catsup Contents 14 oz. Avoir. \* \* \*"**

United States District Court for the Eastern District of New York.

Misc. Nos. 1152 and 1151. October 22, 1947.

Reversed, 168 F. 2d 632. See page 242.

Certiorari denied, 335 U. S. 885 (1948).

Where a food product was condemned because it was adulterated, the district court had the power to permit the exportation of the product under the conditions specified in Section 801 (d).

Sections 304 (a), 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

J. Vincent Keogh, U. S. Attorney, Eastern District of N. Y. (Morris K. Siegel, Assistant U. S. Attorney, of counsel), for plaintiff.

Bergner & Bergner, for defendant.

*[On Reargument]*

KENNEDY, HAROLD M., District Judge: On the application of the United States I granted reargument in the above cases. There was a passage in my original opinion dated July 3, 1947, which indicated that I believed the goods, or some of them, when seized were being packed for export. The affidavit submitted by the government in support of its application for reargument tends to show that my analysis of the facts was erroneous; that these goods were never intended for export, and therefore, the conduct of the claimants was in clear violation of law.

Even so, my determination of the original motion was based upon the idea that under one of the relevant statutes (21 U. S. C. A. § 381d) I had power to permit the export of these goods under proper restrictions;

that I was not required to order them destroyed, where they could not be brought into compliance with law, as is the case here (21 U. S. C. A. § 334d). If that is so, certainly in a proper case there is a clear appeal to the discretion of the court not to compel destruction, but to utilize the food where, as here, it is fit for human consumption, is in accordance with the specifications of foreign purchasers, and is not in conflict with the laws of the country to which it is to be sent.

Therefore assuming, and even finding as a fact, that the claimants did not intend to export the goods, but planned to dispose of them in the domestic market, I still adhere to my original determination.

Settle order.



## RESEARCH LABORATORIES, INC. v. ROBERT E. HANNEGAN, ET AL.

United States District Court for the District of Columbia. Civil  
 No. 3223-47. December 18, 1947.

In a suit for a declaratory judgment brought by the distributor of a drug product involved in post office proceedings and proceedings instituted under the Federal Food, Drug, and Cosmetic Act, the court declared that there was no justiciable controversy; and that the Federal Security Agency, under guise of a suit for a declaratory judgment, cannot be compelled to give an advisory opinion as to some contemplated labeling of the product or as to the criminality of the plaintiff's prospective sales activities.

Sections 301 (a), 303 (a), 304 (a), Federal Food, Drug, and Cosmetic Act.

A declaratory judgment is not a substitute for a new trial or for an appeal from a former judgment deciding identical issues or issues which the court believes were necessarily passed upon.

Sections 301 (a), 303 (a), 304 (a), Federal Food, Drug, and Cosmetic Act.

### Memorandum

McGUIRE, Associate Justice: There is no justiciable controversy here. *Aetna Life Insurance Company v. Haworth et al.*, 300 U. S. 277-240, 241. *Helco v. McNutt*, 137 F. 2d 681, 683, 687.

*Curriu v. Wallace* (306 U. S. 1) can be distinguished. There, there was an actual controversy of a real and substantial character going to the constitutionality of the Tobacco Inspection Act (Aug. 13, 1935) as the Circuit Court held, which view the Supreme Court adopted.

Here, however, no such definitiveness exists. The declaratory judgment is not a substitute for a new trial or for an appeal from a former judgment deciding identical

issues or issues which the court believes were necessarily passed upon. Borchard: *Declaratory Judgments*, 355. Nor can the Federal Security Agency under guise of this remedy be compelled to give an advisory opinion in future or to place its *nihil obstat* on some contemplated labeling of the plaintiff's product—that is neither its established purpose or function.

Again, infraction of Title 21, § 331 U. S. C. A. is a criminal act (§ 333) and what the plaintiff here is actually seeking is an advisory opinion *in limine* as to the criminality or lack of criminality of its prospective sales activities.

Motion to dismiss granted. Counsel will prepare proper order.

## SMITH v. GREAT ATLANTIC & PACIFIC TEA CO.<sup>1</sup>

United States Court of Appeals for the Eighth Circuit. No. 13707.  
 November 5, 1948. 170 F. 2d 474.

The defendant sold to plaintiff spinach which was shipped with inspection certificates from the United States Department of Agriculture attached to the bills of lading certifying the grades. Plaintiff paid the price agreed on and resold some of the spinach, but the remaining part was found on analysis to be unfit for human food because it contained "filth" and was condemned in libel proceedings under the Federal Food, Drug, and Cosmetic Act, to which both plaintiff and defendant were parties. Defendant was fully bound by the decree of condemnation; he knew of the proceedings and appeared generally therein and could not deny that the spinach was rightly ordered destroyed for unfitness. If the spinach may have been merchantable when it moved in interstate commerce, the issue could have been raised in the libel proceedings.

Section 304 (a), Federal Food, Drug, and Cosmetic Act.

<sup>1</sup> This case did not arise under the Federal Food, Drug, and Cosmetic Act.—Author.



The court declared that the spinach, when opened and analyzed, had been found unfit, and that that was evidence that such was its condition when sold.

Section 402 (a), Federal Food, Drug, and Cosmetic Act.

Rex W. Perkins and G. T. Sullins submitted brief for appellant.

E. L. McHaney, Jr. (Thomas B. Pryor, Thomas Brady Pryor, Jr., G. Byron Dobbs, Pryor, Pryor and Dobbs; John M. Lofton, Jr., and Grover T. Owens, and Ehrman & McHaney, were with him on the brief) for appellee.

Before GARDNER, Chief Judge, and WOODROUGH and RIDDICK, Circuit Judges.

*[Appeal To Reverse Judgment]*

WOODROUGH, Circuit Judge, delivered the opinion of the Court: This appeal is taken to reverse a judgment for \$6,495.87 in favor of plaintiff in an action for damages arising out of the sale of certain canned spinach by defendant to plaintiff. The contract for the sale originated in a telegram from defendant (doing business as Smith Canning Co.) to plaintiff A. & P. Tea Company, "Do you want 3300 cases standard twos spinach 1.10 Government Certificate," to which the Tea Company responded, "Will accept certificated spinach offered if last of February shipment okay advise if available our labels." A formal contract followed, by the terms of which the plaintiff bought and defendant sold 3600 cases 24/2 Iona Label Full Standard Spinach at 1.10 dozen to be shipped in box cars each containing 1800 cases of 24 cans with Government Grade Certificate attached to invoice. The goods were shipped with inspection certificates from the United States Department of Agriculture attached to the bills of lading certifying the grades to be U. S. Grade C or U. S. Standard, and before issuing the certificates the inspector of the Department of Agriculture at Fayetteville, Arkansas, inspected the spinach by opening some of the cans in each lot (12 in one and 9 in the other), but it was not disclosed what tests were made by him. Plaintiff paid the price agreed on and resold some of the spinach but the remaining part was found on analysis to be unfit for human food because it contained "filth" consisting of plant lice of the genus known as aphids and was seized and condemned for that reason in libel proceedings under the Food and Drug Act to which both plaintiff and defendant were parties.

*[Decision of Trial Court]*

The trial court concluded that the defendant was liable to plaintiff for the breach of an "implied warranty that the spinach sold shall be of merchantable quality" and the judgment entered was for the propor-

tionate amount plaintiff had paid for the part of the spinach seized and condemned and for freight, handling and storage paid by plaintiff in respect to that part. The court entered findings of fact and conclusions of law and a written opinion directing the judgment which are reported fully at 75 F. Supp. 164. As the issues presented to and decided by the trial court are also clearly shown in the report, and it is accessible, we avoid needless restatement here by referring to it.

On the trial of the case the parties were in accord that the law controlling decision is the law governing sales of personal property in Arkansas where the sale was agreed upon and performed and their contentions were related to the Uniform Sales Act which is in force in Arkansas as Act 428 of the General Assembly of Arkansas, 1941. The court applied subdivision 2 of § 15 of the Act to the stipulated facts as it found them in concluding that there was an implied warranty "that the goods shall be of merchantable quality" and that the warranty was breached when the goods "described" as spinach were determined to be unfit for food. It also concluded that the implied warranty was not "negated" within the intent of Section 71 of the Act by reason of the agreement that the spinach to be shipped was certified U. S. Grade C or U. S. Standard. It concluded that the terms of the contract of sale were not inconsistent with the existence of the warranty implied under subdivision 2. Also that the libel proceedings and decree of condemnation were evidence of infestation and unfitness of the spinach within the time it was to be resold and the breach of the implied warranty.

*[Contentions of Appellant]*

On this appeal the contentions of the appellant in denial of implied warranty and breach thereof are in substance the same as he presented below to the effect that (1) the words of subdivision 2 of § 15 of the Act, "Where the goods are bought by description," are not applicable to the sale in



question and that subdivision 1 of § 15 is the only applicable provision; (2) that by reason of the express agreement in the sale as to certification of the goods and compliance therewith the seller was relieved under subdivision 3 of § 15 of liability for implied warranty; (3) that the agreement as to certification "negatived" any implied warranty by reason of the provisions of section 71 of the Act; (4) that the decision and reasoning of the Supreme Court of Arkansas in *Smith v. Tatum*, 198 Ark. 802, 131 S.W. 2d 619, precluded recovery by plaintiff, and (5) that the proceedings and decree of condemnation did not prove the unfitness of the spinach at the time of the sale.

On careful consideration it appears to us that each of appellant's contentions was met and resolved against appellant by the trial court in accord with permissible determination of Arkansas law.

[Implied Warranty as to Merchantable  
Quality]

(1) Though there appears to be no case in which the Supreme Court of Arkansas has been called on since the state's adoption of the Uniform Sales Law to decide that where a dealer sells canned food there is an implied warranty that the product sold is merchantable as food—fit for human consumption—no reason is shown to anticipate that it would not so declare in view of the statute. In this case there is no question raised as to whether the spinach sold was of a particular grade and § 15 (1) of the Act is without application. It is undisputed that it was not fit for human consumption and was not salable as the food known as spinach. The court rightly held that the sale falls within the provisions of § 15 (2) of the Act and that the seller is liable upon the implied warranty that the goods should be of merchantable quality. *Patrick Ryan v. Progressive Grocery Stores, Inc.*, 255 N.Y. 388, 175 N.E. 105, 74 A.L.R. 339, relied on and quoted from by the district court clearly and fully elucidates the meaning and declares the applicability of those provisions to a case such as is shown by the facts herein as well as the irrelevance to such a case of § 15 (1). Additional cases are cited confirming that the Uniform Sales Law means that a seller who deals in food such as spinach impliedly warrants to one who buys spinach from him that the spinach shall be of merchantable quality—fit for human consumption—and that the seller is liable for breach of such warranty as fol-

lows: *Jax Beer Co. v. Schaeffer* (Texas) 173 S.W. 2d 285 (1943); *Vaccarino v. Cozzubo*, 181 Md. 614, 31 Atl. (2) 316 (1943); *Bob's Candy & Pecan Co. v. McConnell*, 140 Tex. 331, 167 S.W. 2d 511 (1943); *Botti v. Venice Grocery Co.*, 309 Mass. 450, 35 N.E. 2d 491 (1941); *Country Club Soda Co., Inc. v. Arbuckle*, 279 Mass. 121, 181 N.E. 256 (1932); *Giesness v. Scow Bay Packing Co.*, 16 Wash. 2d 1, 132 Pac. 2d 740 (1942); *W. R. Grace & Co. v. National Wholesale Grocery Co., Inc.*, 251 Mass. 251, 254, 146 N.E. 908 (1925); *Griggs Canning Co. v. Josey*, 139 Tex. 623, 164 S.W. 2d 835 (1942); *Kansas City Wholesale Grocery Co. v. Weber Packing Corporation*, 93 Utah 414, 73 Pac. 2d 1272 (1937); *Giant Manufacturing Co. v. Yates-American Machinery Co.*, 8 Cir., 111 F. 2d 360.

[Defect Not Apparent Except on Analysis]

(2) § 15 (3) of the Act which may relieve a seller of goods from liability on account of the implied warranty which is created by subdivision 2, reads:

"If the buyer has examined the goods there is no implied warranty as regards defects which such examination ought to have revealed."

Appellant argues in effect that because the offer and acceptance here disclosed was of spinach inspected and certified U. S. Standard Grade by the federal inspector, the inspector should be deemed the buyer's agent and that the case is therefore one in which "the buyer has examined the goods."

We do not think so. Nothing in the correspondence or contract indicated any intention of the Tea Company to designate the U. S. Marketing Service as its agent to examine the goods and the parties stipulated that neither of the parties know what tests were made by the inspector. But this court had occasion in *Giant Manufacturing Co. v. Yates-American Machine Co.*, 111 F. 2d 360 (1940), to consider the meaning and intent of § 15 (3) of the Act. That was an action to recover the purchase price of coil units to be used by the buyer in air conditioning equipment. Although the buyer's agent went to the seller's plant and the coils were tested in his presence, it appeared that his examination was not such as ought to have revealed the leakage faults afterwards shown to have rendered the coils unmerchantable and we held the seller not relieved of liability by § 15 (3).

In *Barrett Co. v. Panther Rubber Co.*, 1 Cir., 24 F. 2d 329 (1928), the construction



of subdivision 3 of § 15 of the Act was involved. The court said:

"The tests bound the plaintiff only as to what was, or properly could have been, disclosed by reasonable testing. The testimony constrains us to find that there was nothing revealed by the tests or otherwise to indicate that after a lapse of time the goods sold would develop a bloom or other defect making the heels unmerchantable; that there was no defect discoverable by the exercise of ordinary experiments; that the defect was in fact not discovered until later by cobblers. Tests are not conclusive, one way or the other. In the case before us we find from the proofs that, after the tests, the buyer—the plaintiff—still had the right to rely upon the seller's judgment and skill, and in fact did so rely. *Carlton v. Lombard, etc.*, 149 N.Y. 137, 43 N.E. 422; *Kellogg Bridge Co. v. Hamilton*, 110 U.S. 108, 3 S. Ct. 537, 28 L. Ed. 86; *Bierman v. City Mills Co.*, 151 N.Y. 482, 45 N.E. 856; 37 L.R.A. 799, 56 Am. Rep. 635. The evidence clearly shows that the plaintiff suffered damages by reason of the defendant's fault. What were the damages?"

The same conclusion follows on the facts here. Furthermore, § 14 of the Act applying to sales by sample as well as by description fully preserves the implied warranty by the seller of the merchantable quality of the goods, even if the federal inspector should be deemed the buyer's agent. Though the few cans of spinach examined by the inspector may not have contained aphids, the buyer would not be precluded from recovery on the warranty of merchantable quality of the spinach by the inspector's examination in the absence of any showing that the examination ought to have disclosed the infestation of the spinach. The defect was disclosed on analysis and there is no showing that it was otherwise apparent.

*[Implied Warranty Not Negatived by Course of Dealing]*

(3) As to the provisions of § 71 of the Act which permit a liability arising from implied warranty to be negatived or varied by express agreement, course of dealing or custom, we find nothing in the transaction here from which it could be inferred that there was any express agreement, course

of dealing or custom to make the section applicable. The trial court's conclusion that the defendant canning company had no intention of selling spinach that was not merchantable and that the plaintiff Tea Company did not intend to buy a product that could not be resold to the public for food, is in accord with the evidence, and there were no circumstances of the sale relieving the seller from the implied warranty.

*[Cited Case Not Applicable]*

(4) The decision of the Supreme Court of Arkansas in *Smith v. Tatum, supra*, was rendered before the adoption in the state of the Uniform Sales Law and can in no wise be regarded as interpretative of the present Act. It was rested in part upon the State Pure Seed Act and is without application to the present case.

*[Appellant Bound by Decree of Condemnation]*

(5) As to the sufficiency of the decree of condemnation to show the unfitness for food of the unsold part of the spinach remaining in plaintiff's possession at the time it was seized under the libel against it, we find no error in the ruling of the trial court that appellant was fully bound by the decree. He knew of the proceedings and appeared generally therein and cannot be heard to deny that the spinach was rightly ordered destroyed for unfitness. If, as he now suggests, the spinach may have been merchantable when it moved in interstate commerce and became unmerchantable afterwards, he could have raised the issue in the case. The spinach when opened and analyzed was found unfit and that is evidence that such was its condition when sold. *American Soda Fountain Co. v. Medford Grocery Co.*, 128 Or. 83, 262 Pac. 939 (1928). It is not suggested that there was any possible way for the spinach to have become infested with the plant lice which rendered it "filthy" as adjudicated, except that the defect existed in some stage at the time of the sale.

*[Judgment Affirmed]*

We find no error in the judgment.

Affirmed.



STINSON CANNING COMPANY AND AMERICAN SURETY  
COMPANY, (399 CASES, MORE OR LESS, BEACH CLIFF  
BRAND MAINE SARDINES, ETC.), v. UNITED STATES

United States Court of Appeals for the Fourth Circuit. No. 5802.

November 10, 1948. 170 F. 2d 764.

Certiorari denied, 336 U. S. 951 (1949).

On the Government's motions to forfeit bonds filed pursuant to Section 304 (d), the district court entered judgments in favor of the Government. The decrees of condemnation had provided that the claimant might retake possession of the condemned foodstuffs to segregate the good from the bad, but the segregation was not accomplished within the period of time specified by the district court. The Court of Appeals held that even if it assumed that the district court had the discretionary power to remit all or a portion of the bonds upon a finding that the breach was inadvertent, there was no abuse of this discretion under the facts involved in decreeing a forfeiture.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

The court stated that it agreed with the district court's ruling which denied claimant's motion for permission to export the condemned merchandise.

Sections 304 (d), 801 (d), Federal Food, Drug, and Cosmetic Act.

The court declared that the claimant had offered an utterly insufficient excuse for grossly neglectful behavior in not complying with the provisions of the bond within the period specified by the district court.

Section 304 (d), Federal Food, Drug, and Cosmetic Act.

Huger Sinkler and Robert E. McCarthy for appellants.

Louis M. Shimel, Assistant U. S. Attorney, (Ben Scott Whaley, U. S. Attorney, on brief) for appellee.

Before PARKER, SOPER and DOBIE, Circuit Judges.

DOBIE, Circuit Judge: These are eight appeals from eight identical orders of the District Judge granting judgments against the appellants, Stinson Canning Company and American Surety Company, on performance bonds filed by appellants pursuant to 21 U. S. C. A. § 334 (d). The aggregate amount of the judgments is \$20,020. The reasons for granting judgments on the several bonds were identical so the appeals were consolidated.

During April of 1947, the United States, acting through the Pure Food and Drug Administration, instituted in the District Court libel proceedings under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. §§ 301 *et seq.*, against eight lots of canned sardines. The libels, identical in each instance, alleged that the sardines were diseased and sought their condemnation and forfeiture. The appellant, Stinson Canning Company, intervened and claimed ownership of the sardines. Thereafter, on October 11, 1947, identical consent decrees were entered reciting the claimant's admission of the allegations of the libels and its consent to judgments that the sardines be condemned.

*[Claimant Permitted To Repossess Goods]*

As is not infrequent in cases of this sort, the decrees provided that the claimant might retake possession of the condemned foodstuff upon posting a bond in an amount roughly equal to the value of the sardines. This was done to give the claimant an opportunity to segregate cans or cases containing diseased fish from those containing fish not diseased. If this segregation proved practicable, only those cans or cases containing diseased fish were to be destroyed; otherwise the entire lot was required to be destroyed. The segregation and destruction were to be done under the supervision of the Pure Food and Drug Administration and were to be accomplished within three months following the entry of the decrees. Suitable bonds conditioned upon compliance with the terms of the decrees were given by the appellant, Stinson Canning Company, as principal, and the appellant, American Surety Company, as surety. The appellant, Stinson, then caused the sardines to be shipped to its plant in Maine, where it was intended that they be segregated under the supervision of the Boston Station of the Pure Food and Drug Administration.



*[Performance Deadline Extended 90 Days]*

On January 19, 1948, after application had been made by appellants for a sixty-day extension of time, the District Judge entered an order extending for a period of ninety days from that date the time for the performance required by the original decrees. The order expressly provided: "that the Claimant shall fully comply with the provisions of the said Decrees not later than ninety (90) days from the date hereof and that no further extension shall be applied for by the said Claimant." This ninety-day period expired on April 18, 1948.

*[Order for Judgment on the Bonds]*

On May 25, 1948, the United States Attorney served notice that on June 7, 1948, he would move for an order for judgment on the bonds since, it was alleged, the appellants had not complied with the decrees. No written return was ever served or filed in opposition to the motion and the allegations of non-compliance were never in any way controverted. At the hearing on the motion on June 7, attorneys for the appellant, Stinson Canning Company, appeared and made an oral statement to the Court in which they admitted non-compliance with the decrees but tendered an explanation, or excuse, for their failure in this respect. During the course of this statement, counsel several times offered to repeat statements and opinions expressed by various parties, none of whom was present in court or called as a witness. The Trial Judge properly excluded these statements as hearsay and as having no place in a return. Counsel then asked for an opportunity to present the testimony of a member of the Boston Station who presumably was at that time in Boston, where it would have been necessary to take this member's deposition. The Judge stated that counsel might produce any witnesses then in court but refused to stay the proceedings to afford counsel the opportunity of procuring additional evidence.

After hearing counsel's statement, the District Judge found that appellants had not complied with the decrees, that the conditions of the bonds had therefore been breached and ordered judgment against appellants on each of the bonds in its full amount.

*[Questions Presented by the Appeals]*

The substantial questions presented by the appeals are: (1) Did the District Judge have the power, in his discretion, to remit

all or a part of the bonds if the breach of their conditions was not wilful or grossly neglectful; (2) If he had that power, was there an abuse of discretion on the facts of this case; and (3) Did the District Judge err in refusing a continuance to give the appellants an opportunity to procure the testimony of the desired witnesses?

*[No Abuse of Discretion]*

We refrain from deciding the question whether the District Court had the power to remit all, or a portion, of the bonds in question, upon a finding that the breach of the conditions of the bonds was not wilful but was the result of inadvertence and was no more than a technical failure to comply with these conditions. The decision of this question is not necessary to the disposition of the instant case.

If we assume, without deciding, that the District Judge had the discretionary power to remit, we think upon the facts in this case that there was no abuse of this discretion in his decreeing a forfeiture of the bonds.

*[Dilatory Conduct on the Part of Claimant]*

The original decrees were entered on October 11, 1947, and the period for their performance, as extended, did not expire until April 18, 1948. Appellants thus had more than six months in which to comply. Further, the Government did not move for forfeiture of the bonds for an additional month (May 25, 1948), and the hearing on that motion was not held until June 7, 1948. It is quite possible that the District Judge would have been more receptive to appellants' explanation had they come into court on June 7 and stated, even at that late date, that they had complied. But appellants admit that they failed to carry out the decrees for the entire period from October 11, 1947, to June 7, 1948—a period of almost eight months.

The record shows that the Boston Station of the Pure Food and Drug Administration cooperated in every way with appellants, that it was ready at all times to supervise the segregation or destruction of the sardines and that it so notified appellants. The appellants, however, failed to notify the Boston Station of the arrival of the sardines and even failed to maintain the identity of the separate lots in the eight seizure actions. A letter from the Chief of the Atlanta Station to the United States Attorney in charge of the cases states: "\* \* \* despite our efforts to cooperate with the claimant we have



found that there has not been a bona fide attempt to comply with the provisions of these several decrees." And as late as May 21, 1948, the Boston Station reported that the claimant had not destroyed the sardines or even indicated that it intended to do so, and had not paid the claim for costs of supervision.

*[Intention To Export the Sardines]*

In the face of this, at best, extremely dilatory conduct, we need examine only briefly appellants' explanation of their failure to comply with the decrees. The proceeding in the court below was one of a dozen or more identical actions instituted in federal district courts throughout the country against other lots of canned sardines in which the appellant, Stinson Canning Company, was interested. The sardines were all subject to the same fungus disease, a disease on which the Pure Food and Drug Administration allows a tolerance of only five per cent. It appears, however, that other countries permit a higher tolerance. Believing that the sardines would all come within the tolerance permitted abroad, Stinson, in a proceeding in the Western District of New York, at Buffalo, moved that the decree be amended to permit exportation, the ruling on which motion was still pending. Counsel for Stinson then informed a member of Boston Station that it was his intention to use the Buffalo case as a test case and to abide by its disposition with respect to the other cases throughout the country, and "gained the impression that his suggestion met with approval." Appellants depend upon their reliance on this agreement to excuse their non-performance of the decrees below. By appellants' own admission, however, the policy of the Food and Drug Administration in Washington is to oppose permission to export goods which have been declared unfit for shipment in interstate commerce on the theory that such permission would encourage negligence on the part of packers. When, belatedly, at the hearing of June 7, 1948, appellants moved for permission to export the sardines here involved, the District Judge denied the motion. While we may state that we agree with his ruling in this respect, it is immaterial that we do or do not. The member of the Boston Station was patently without authority to bind the Government to treat the Buffalo case as a

test case, certainly was without authority to amend the decrees below in any such manner, and the appellants were entirely without right to rely on his agreement in this respect.

The appellants might readily have moved below for a further extension pending the outcome of the Buffalo case, or might have made a motion, similar to that made in the Buffalo case, that the decrees be amended to permit exportation. Until the time for performance had long since expired, they did neither. As we have already stated, the order of January 19, 1948, granting the ninety-day extension, provided "that the Claimant shall fully comply with the provisions of said Decrees not later than ninety (90) days from the date hereof and that no further extension shall be applied for by the said Claimant." Despite this clear and positive mandate, the appellants did nothing at all even to apprise the court of the course they were pursuing. They have offered an utterly insufficient excuse for such grossly neglectful behavior. To require the courts to permit their decrees to be amended by such out-of-court agreements with third parties as is here before us would create chaos in the enforcement of these decrees.

*[No Error in Refusal To Continue Proceedings]*

Finally, there was no error in the refusal to continue the proceedings to permit appellants to procure the testimony of certain witnesses. Appellants received due notice that the hearing of the motion to forfeit was to be held on June 7, 1948. They had ample opportunity to procure any evidence they wished to present. Even if it is considered that a formal motion for a continuance was made, no testimony was offered to sustain that motion. Appellants did not claim a diligent attempt by them to procure the desired testimony or offer a reasonable excuse for their inability to present this testimony on the date for which the hearing had long been set. But apart from the technical defects in appellants' position and entirely on practical considerations, the conduct of appellants as outlined above did not entitle them to any further consideration.

*[Judgments of Forfeiture Affirmed]*

The judgments of the District Court forfeiting the bonds are affirmed.



*U. S. v. 5 Cases, etc., Figlia Mia Brand, etc.*

**FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC., APPELLANT v. UNITED STATES OF AMERICA, APPELLEE**

United States Court of Appeals for the Fifth Circuit. No. 12033.

February 1, 1949.

Reversed, 336 U. S. 804 (1949). See page 560.

See pages 212, 249.

The court of appeals held that it had been reversed by the Supreme Court on one point: that certain advertising matter shipped separately from the machines in question might constitute "labeling" if the movements of advertising and machines were a single interrelated activity. The court declared that it did not appear whether there had been a single interrelated activity as to each shipment or as to which shipments, and that that appeared to be a question which should be further investigated.

Section 201 (m), Federal Food, Drug, and Cosmetic Act.

Before SIBLEY, HUTCHESON, and HOLMES, Circuit Judges.

By the Court: Our judgment in this case, reported 164 Fed. (2) 245, was reversed in *United States v. Fred Urbeteit*—U. S.—and the cause remanded to us for further proceedings in conformity with the opinion of the Supreme Court. The reversal was on the one point, that certain advertising matter shipped separately from any of the machines and held by us for that reason not to have "accompanied" any of them might nevertheless constitute "labeling," if the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones. There were four or five shipments of machines several weeks apart, and only one shipment of advertising. It does not appear

whether there was a single interrelated activity in machines and advertising as to each shipment, or as to which shipments. That appears to be a question which should be further investigated.

[Cause Remanded to District Court]

The Supreme Court did not disturb our former ruling that the district court should have heard all the evidence offered on the question of the falsity of the advertising. We adhere to that ruling. The judgment of the district court is accordingly reversed and the cause remanded for further proceedings in conformity with the opinion of the Supreme Court and with this opinion.

Judgment reversed.

**UNITED STATES OF AMERICA v. 5 CASES, MORE OR LESS, Each Containing 6 Cans of an Article Labeled in Part: (Can) "Figlia Mia Brand a Blend Consisting of 90% Vegetable Oils, Choice Cottonseed, Corn and Peanut Oils, Plus 10% Pure Olive Oil One Gallon Net" and 5 Cases, More or Less, Each Containing 6 Cans of an Article Labeled in Part: (Can) "Pace O Mio Dio Brand 80% Choice Peanut Oil and 20% Pure Olive Oil One Gallon Net"**

United States District Court for the District of Connecticut. Admiralty  
Nos. 4359 to 4363. February 4, 1949.

Seizure proceedings were instituted against cans of oil alleged to be adulterated and misbranded. The claimant moved for an order requiring the Government to produce copies of "each and every chemical test and analysis" made by the Government on samples taken from the seized merchandise. The court held that the proceeding, while commencing as a libel under the Admiralty Rules, was an action at law at that stage and was governed by the Federal Rules of Civil Procedure.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.



The Federal Rules of Civil Procedure governing the discovery process have been liberally construed; but there are limitations, particularly with reference to Rule 34.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Discovery and production of documents under Rule 34 is not a matter of right, and the language of the rule must be read in the light of the general principles governing the application of Rules 26 to 37, inclusive, of the Federal Rules of Civil Procedure, embracing depositions and discovery.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

Even under the most liberal construction of Rule 34, mere assertions of threatened prejudice are not enough. The court must be satisfied that the production of the requested document is necessary to enable a party to prepare his case, or that it will facilitate proof or progress at the trial.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The court held that the claimant had not adequately met the requirement of Rule 34, namely, a good cause for the discovery; concededly the claimant had had opportunity to make its own tests and analyses which might be offered in evidence in defense against a forfeiture.

Sections 304 (a), 304 (b), Federal Food, Drug, and Cosmetic Act.

The court declared that such holding was compatible with the Federal Food, Drug, and Cosmetic Act, which expressly enumerates fresh fruits and vegetables as the only types of products concerning which a claimant is entitled to a true copy of the analysis.

Section 304 (a), 304 (b), 304 (c), Federal Food, Drug, and Cosmetic Act.

[*Claimant's Position*]

HINCKS, C.C., District Judge: This action arises out of a libel by the Government, pursuant to Section 334 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Sec 301, *et seq.*, resulting in a seizure of five cases more or less of cans of oil, alleged to have been adulterated and misbranded. It is presently before the Court on a motion by the Antonio Corrao Corporation, as claimant of the libeled merchandise, for an order requiring the government to produce true and exact copies of "each and every chemical test and analysis" made by the government on the samples taken by it from the seized merchandise. The gist of the claimant's position is that the allegations of the libel do not reveal the nature of the alleged adulteration with exactitude; that the claimant is entitled to know the specific substances and exact percentages thereof with which the government asserts claimant adulterated the oil; and that the rights of the claimants will be seriously prejudiced unless prior to trial the claimant should be allowed to inspect the chemical analyses made by the government's experts which, presumably, will constitute the basis of the prosecution. The claimant contends that he is entitled to this inspection under Rules 26, 33, and 34 of the Federal Rules of Civil Procedure.

[*Position of Libelant*]

In opposing the motion the libelant relies first upon the strict exclusiveness of the language used in Section 334(c) of the Act allowing a claimant a true copy of the analysis upon which the proceeding is based only where a fresh fruit or vegetable is involved and second on the theory that the libelant should not be required to disclose expert testimony or opinions of its chemists who analyzed the oil seized, particularly in the absence of the claimant's showing of necessity or of hardship resulting from the denial.

[*Support for Claimant's Contention*]

This proceeding while commencing as a libel under the Admiralty Rules, nevertheless at this stage is an action at law and is governed by the Federal Rules of Civil Procedure. *Four Hundred and Forty-three cases of Frozen Egg Product v. U.S.*, 226 U.S. 172, 183; *U.S. v. 935 Cases Tomato Puree*, 136 F. 2d. 523; *Reynolds v. U.S.*, 153 F. 2d 929, 931. The claimant's request for production and inspection of the tests and analyses made by the libelant comes within the scope of Rule 34.

There is much support for claimant's contention that the Rules of Civil Procedure governing the discovery process have been liberally construed. 3 Moore's *Federal*



*Practice*, Sec. 34.04, *Hickman v. Taylor*, 329 U.S. 495, 507; *United States v. 300 Cases of Black Raspberries*, 7 F.R.D. 36, 37; *Stark v. American Dredging Co.*, 3 F.R.D. 300. But this liberal construction of disclosure before trial has not developed without limitations. As the Supreme Court noted in *Hickman v. Taylor*, *supra*, “. . . discovery like all matters of procedure has ultimate and necessary boundaries”. And this is particularly true with reference to Rule 34 under which claimant presently seeks relief.

[Rule 34]

Discovery and production of documents under Rule 34 is not a matter of right, *Sutherland Paper Box Co. v. Grant Paper Box*, 8 F.R.D. 416, 417. This rule, by its very language, is more rigid than rules relating to depositions and interrogatories, and to entitle the applicant to the order prayed for he must show good cause therefor, designate the documents desired, and show that they are not privileged and are material to the matter involved. *Martin v. Capital Transit Co.*, 170 F. 2d 811; *Heiner v. North American Coal Corp.*, 3 F.R.D. 63. And this language of Rule 34 must be read in the light of the general principles governing the application of the Federal Rules, 26-37 inclusive, embracing Depositions and Discovery. In *Hickman v. Taylor*, *supra*, the Supreme Court recently enunciated a principle of discovery limiting disclosures to those instances wherein the denial of the same would unfairly prejudice the party seeking inspection in preparing his claim or would cause him undue hardship or injustice. Cf. 2 Moore's *Federal Practice*, 1947 Cumulative Supplement, Sec. 26.12, p. 172.

What constitutes “good cause” is a difficult question, and as the learned editor has suggested in 2 Moore's *Federal Practice*, Sec. 34.04, considerations of practical convenience are of prime importance. But even under the most liberal construction of this rule, mere assertions of threatened prejudice are not enough. The Court must be

satisfied that the production of the requested document is necessary to enable a party to prepare his case, or that it will facilitate proof or progress at the trial. *Hickman v. Taylor*, *supra*, 509, *Gordon v. Pennsylvania R. Co.*, 5 F.R.D. 510, 512.

[Requirement Not Met by Claimant]

Even with the liberal objective of the Federal Rules in mind I fail to see where the claimant has adequately met the requirement of Rule 34—namely, a good cause for the discovery. Concededly the claimant has had opportunity to make its own tests and analyses which may be offered in evidence in defence against a forfeiture. With such authentic evidence within ready reach I cannot find that the claimant will suffer unfair prejudice if not accorded a preview of the government's evidence.

This holding is altogether compatible with the Federal Food, Drug and Cosmetic Act which expressly enumerates fresh fruits and vegetables as the only types of products concerning which a claimant is entitled to a true copy of the analysis. Apparently Congress realized that the tendency of such fresh produce to spoil left a claimant with scant opportunity for useful and necessary inspection of his own and that consequently, in fairness, the Government report should be made available to him. But that is not the case here.

From this conclusion I cannot recede even though it be deemed at variance with the holding in *United States v. 300 Cases of Black Raspberries*, *supra*. With all deference, I cannot see the necessity of a court order to enable a claimant to pierce “the dark veil of secrecy over pertinent facts” when without an order he can poke his head within the veil and make his own observation of the facts.

[Motion Denied]

It is accordingly ordered that the motion be denied.

---

UNITED STATES v. 12 BOTTLES OF ESTEREX<sup>1</sup>

United States District Court for the Eastern District of Missouri. May 2, 1946. Notices of Judgment under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949.

Seizure proceedings were instituted against a product entitled “Cosco Esterex,” which contained monochloroacetic acid, on the ground that it was

---

<sup>1</sup> These findings properly belong in the “Seizure Cases” division of this book, but were issu-

ed in a Notice of Judgment after that division had gone to press.—Author.



misbranded since the name of the product, coupled with the directions for use, represented that the article was wholesome and suitable for use as a component of beverages for man, whereas the article contained about 15 grams of monochloroacetic acid per 100 cc., which is a poisonous substance, and the labeling failed to reveal the material fact that the article contained such a substance. The trial judge, in his findings of fact, declared that, although there was no statement on the label which was untrue, the label was misleading in that it failed to reveal that the article contained a poisonous substance, and that such a fact was material in the light of the representation that the article was to be used as a component of liquids for human consumption.

Sections 201 (f), 201 (n), 304 (a), 403 (a), Federal Food, Drug, and Cosmetic Act.

The trial judge declared that, in determining whether labeling is misleading, there shall be taken into account whether it fails to reveal any fact material in the light of representations made on it, or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual.

Section 201 (n), Federal Food, Drug, and Cosmetic Act.

The purpose of the Federal Food, Drug, and Cosmetic Act is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous.

Title, Federal Food, Drug, and Cosmetic Act.

The trial judge concluded that the labeling on the article proceeded against was misleading in that it failed to reveal that the article contained a poisonous substance.

Sections 201 (n), 304 (a), 403 (a), Federal Food, Drug, and Cosmetic Act.

### Findings of Fact

DUNCAN, District Judge: 1. The United States Marshal on October 23, 1945, seized twelve bottles labeled in part "Cosco Esterex" in the possession of Moore Brothers Bottling Company, 1711 North Spring Avenue, St. Louis, Missouri, within the Eastern Division, Eastern Judicial District of Missouri.

2. The C. O. and W. D. Sethness Company, a Corporation organized and existing under the laws of the State of Illinois, Claimant herein, is the owner of the article seized herein.

3. The C. O. and W. D. Sethness Company, Claimant herein, shipped said article seized herein in interstate commerce from Chicago, Illinois to St. Louis, Missouri, via Hayes Freight Lines on or about July 31, 1945.

4. When the said article was shipped in interstate commerce, each bottle was labeled: "Cosco Esterex—Trade Mark—Manufactured Exclusively by C. O. and W. D. Sethness Company—1926 Sunnyside Avenue, Chicago 40, Illinois—Esterex is a buffered aqueous solution of monochloroacetic acid and its selected esters, salt, and

glycerine—Directions—For stabilizing purposes use  $\frac{1}{2}$  ounce to each gallon of bottling syrup, or to 6 gallons of finished drink—Follow Directions Carefully—Caution—Esterex is not a finished food and should not be taken internally in its present concentration. In common with many acid solutions of low p. h., care should be taken to avoid spillage or breakage. If Esterex in its undiluted form comes in contact with skin or clothing, wash immediately with warm water and then with a solution of baking soda or other mild alkali."

5. The said article seized herein contains 15 grams of monochloroacetic acid per 100 cubic centimetres.

6. Monochloroacetic Acid is a poisonous, toxic and caustic substance.

7. The said article seized herein is intended by its producer, claimant herein, to be used as a stabilizer or preservative of liquids for human consumption, that the producer sells "Cosco Esterex" only to manufacturers for use as a stabilizer for liquids for human consumption and does not sell to wholesalers or retailers for resale or to the consuming public.

8. The label contained on each bottle of



said article represents to purchasers that the said article is to be used as a stabilizer of liquids for human consumption.

9. There is no indication on the label that the said article is poisonous or deleterious to public health.

10. There is nothing on the label to indicate that monochloroacetic acid is poisonous, and the label does not sufficiently caution the careless, the unthinking or the ignorant of the fact that the said article contains a poisonous, toxic and caustic substance.

11. On the label under the Caption "Caution" appears "ESTEREX is not a finished food and should not be taken internally in its present concentration. In common with many acid solutions of low p. h., care should be taken to avoid spillage or breakage." And in smaller type: "If Esterex in its undiluted form comes in contact with skin or clothing, wash immediately with warm water and then with a solution of baking soda or other mild alkali." However, there is no indication on the label as to what the effect of spilling this solution on clothing or skin may be, or what the object of washing may be or that the said article may be poisonous or deleterious to public health.

12. Although the said article is sold only to manufacturers of soft drinks to be used as a stabilizer all manufacturers of soft drinks are not informed as to the properties of monochloroacetic acid and the label would not inform them that the said article contained a poisonous substance.

13. Although there is no statement on the label which is untrue, the label is misleading in that it fails to reveal that the said article contains a poisonous, toxic and caustic substance and such fact is material in the light of the representation that said article is to be used as a component of liquids for human consumption.

#### Conclusions of Law

1. The label appearing on each bottle of said article is labeling within the meaning of the Food, Drug and Cosmetic Act of 1938, as amended. (21 U.S.C.A. 321 (m))

2. The said article is a component of

food and is therefore a food. (21 U.S.C.A. 321 (f))

3. In determining whether labeling is misleading there shall be taken into account whether the labeling fails to reveal any fact material in the light of representations made on the labeling or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual. (21 U.S.C.A. 321 (n))

4. As said in *United States v. 62 Packages \* \* \* Marmola Tablets*, 48 Fed. Supp. 878, 1. c. 887:

"The Federal Food Drug and Cosmetic Act was not made for experts nor is it intended to prevent self-medication. The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking and the credulous, who, when making a purchase, do not stop to analyze."

5. The labeling on said article is misleading in that it fails to reveal that the said article contains a poisonous, toxic and caustic substance and said fact is material in the light of the representation that said article is to be used as a component of liquids for human consumption.

6. The labeling in the cause herein is misleading and should contain the definite information that monochloroacetic acid is poisonous.

7. The said article seized herein was misbranded while in interstate commerce.

8. The said article was seized in the Eastern District of Missouri, Eastern Division.

9. On the facts heretofore found, libellant is entitled to condemnation and forfeiture of said article and for costs to be assessed against the claimant.

[On May 2, 1946, judgment of condemnation was entered and the product was ordered destroyed. A motion for a new trial and a motion to amend the findings of fact and conclusions of law was subsequently filed on behalf of the claimant, but were overruled by the court on June 14, 1946.]



**UNITED STATES OF AMERICA v. 104 CASES, MORE OR  
 LESS, Each Containing 30 Packages of an Article Labeled  
 In Part: "Colorado Gold Brand Creamery Butter  
 First Quality One Pound Net"<sup>1</sup>**

United States District Court for the Southern District of California, Central  
 Division. No. 8520, PH Civil. January 5, 1949.

Seizure proceedings were instituted against butter on the ground that it was misbranded since it was represented as first quality butter but was not in fact of such quality by reason of its smell and flavor. The court directed attention to the provision of Section 401, that no definition and standard of identity and no standard of quality shall be established for butter, and stated that an effort to establish a standard of flavor depending on the taste of the butter inspector at a given moment was an effort to establish not only a standard of quality but also a "standard of identity."

Sections 304 (a), 401, Federal Food, Drug, and Cosmetic Act.

The court declared that, from hearing the witnesses testify, and from seeing samples of the butter, the evidence was wholly unsatisfactory to sustain the contention of the Government that the butter did not meet the standards prescribed with relation to flavor, taste, and smell, even if such regulations should ultimately be held valid.

Sections 304 (a), 401, 403 (a), Federal Food, Drug, and Cosmetic Act.

HALL, District Judge: In spite of the extended argument of the government, the long and short of the government's position is that they are attempting to libel the product involved on the basis of regulations concerning flavor. Although the regulations themselves appear of doubtful validity as an unlawful delegation of power, it is unnecessary to go into that proposition or consider it, as no amount of argument can overcome the plain provision of the Act of Congress, which by a specific Section (21 U.S.C. 321(a)) defines butter and prescribes that "it shall contain not less than eighty per cent (80%) by way of milk fat," and which must be read as an intention of Congress to be the only standard of quality with relation to butter, in view of the speci-

fic prohibition in Sec. 341 of Title 21, that no definition and standard of identity, and no standard of quality shall be established for butter \* \* \* ." Certainly an effort to establish a standard of flavor depending upon the taste of the butter inspector at a given moment is an effort to establish not only a standard of quality, but also a "standard of identity."

Moreover, from hearing the witnesses testify, and seeing the butter itself, or samples thereof, the evidence is wholly unsatisfactory to sustain the contention of the government that it does not meet the standards prescribed with relation to flavor, taste, and smell, even if such regulations should ultimately be held valid.

**UNITED STATES v. PINAUD, INC.<sup>2</sup>**

United States District Court for the Southern District of New York. January  
 23, 1947. Notices of Judgment under the Federal Food, Drug, and  
 Cosmetic Act, Cosmetics (No. 152) Issued February 1949.

The defendant was prosecuted on the ground that it had sold Eau de Quinine which was misbranded because the labeling would cause one to believe that there was a substantial amount of quinine in the product, whereas

<sup>1</sup> This decision properly belongs in the "Seizure Cases" division of this book, but was issued after that division had gone to press.—Author.

<sup>2</sup> This charge properly belongs in the "Criminal Cases" division of this book, but was issued in a Notice of Judgment after that division had gone to press.—Author.



the amount was inconsequential. In charging the jury, the trial judge stated that deception may result from the use of statements not technically false or which may be literally true; the purpose of the statute is to prevent misbranding resulting from ambiguity as well as from statements which are false.

Sections 301 (a), 303 (a), 602 (a), Federal Food, Drug, and Cosmetic Act.

The trial judge declared that the courts have held that, through long usage, the name of a product sometimes requires a secondary meaning, as, for example, "Coca-Cola." The trial judge charged that a product might be in violation of the Act because of a misleading name in the early period of its sales, whereas the same product might no longer be in violation if, because of long usage, the public believed it to be that particular product rather than that it contained substantial amounts of the ingredients designated in its name.

Sections 301 (a), 303 (a), 602 (a), Federal Food, Drug, and Cosmetic Act.

The trial judge declared that the test was not whether there was anyone in the United States, regardless of his intelligence or literacy, who might be misled by the name "Eau de Quinine," but that the test was whether the public was likely to be misled by the name—that the goods were misbranded if they bore any statement which might deceive or mislead any purchasers who were of normal capacity and used that capacity in a common sense way.

Sections 301 (a), 303 (a), 602 (a), Federal Food, Drug, and Cosmetic Act.

WATKINS, District Judge: At the conclusion of the evidence by counsel in this case it becomes the duty of the Judge to instruct you as to the law of the case, and when you go to your jury room it becomes your duty under your oath to apply the law as I give it to you to the facts as you found them and reach a just and fair verdict. The Congress of the United States has seen fit to pass what is known as the Federal Food and Drugs Act. That Act is plain and direct. It provides, among other things, that any person or corporation who introduces or delivers for introduction into interstate commerce any food, drug, or cosmetic that is adulterated or misbranded has committed a criminal offense.

*[Instructions as to the Law]*

Another provision of the Act provides that a cosmetic is deemed to be misbranded if its labeling, or if the label on it is false or misleading in any particular. Deception may result from the use of statements not technically false or which may be literally true. The purpose of the statute is to prevent that misbranding resulting from ambiguity as well as mere statements which are false. Those which are ambiguous and tend to mislead our public are in violation of the Act. The purpose of the Food and Drugs Act is for the protection of the consuming public. Those who ship in interstate commerce products coming within the scope of

its protection must do so at their own risk if the standards of the Act are not observed. In any criminal prosecution such as this there are certain general principles of law which apply. First, a defendant is presumed to be innocent until he is proven guilty. While the accused at the beginning of the trial is presumed to be innocent beyond a doubt, when more proof shows beyond a reasonable doubt that the defendant is guilty, then the presumption of innocence disappears completely from the case. Another proposition which applies in all criminal cases is that this defendant now incorporated cannot be found guilty by the jury until you are satisfied beyond a reasonable doubt that the defendant did that with which it is charged in this Information. By reasonable doubt is meant not a capricious doubt, not a doubt which may flit through the minds in considering this case but a substantial doubt which you are called upon to give. By reasonable doubt, I do not mean to say beyond any possible doubt or any imaginary doubt, the words mean exactly what they say. Beyond a reasonable doubt and until you find that the defendant is guilty beyond a reasonable doubt, you cannot return a verdict of "guilty" against the Corporation.

*[Charges Brought by the Indictment]*

The indictment in this case is founded upon this Food, Drug, and Cosmetic Act.



It charges that this defendant in late 1945 sold a quantity of Eau de Quinine to the Gladiator Company located here in the City of New York. It charges that on the invoice of that shipment there was a guarantee to the effect that the product complied with all the requirements of the Food, Drug and Cosmetic Act, including that portion of the Act which forbids a misbranding. Later the Gladiator Company shipped that product into the State of Pennsylvania. The indictment charges that the defendant has violated this Act because the indictment charges that the product, Eau de Quinine was misbranded, the label on it was misleading; the indictment charges that it was misleading because the labeling would cause one to believe that there was a substantial or a consequential amount of quinine in it; whereas the indictment charges that as a matter of fact the amount of quinine in the product, Eau de Quinine was in fact very trivial or inconsequential and the Government contends because of the inconsequential amount of quinine in the product that people buying it are apt to be misled in believing that they are getting a product which contains a substantial or consequential amount of quinine when in fact they are not getting it. That is what the indictment charges.

*[Defendant's Contentions]*

The defendant has entered a plea of not guilty to these charges and has denied that it has misrepresented or misled the public or that the label on its product in any way tends to mislead the public. The defendant contends that this product was manufactured first more than ninety (90) years ago by Edward Pinaud and that through the spending of much money in advertising and through a continued business to a large degree in this product over a period of almost a century that the words: "Eau de Quinine" have come to designate to the public the name of a product, and that they do not represent to the buying public, because of this long usage, the name of a product containing any particular amount or any amount of quinine. Now in nearly all criminal cases there are certain facts which are not indisputable, and that is true in this case. There is no dispute over the fact that this product contains only about two parts of quinine to ten thousand of the product, of the finished product, and there is no dispute over the fact that that amount of quinine, such amount of quinine is a very small or very inconsequential amount of

quinine. There is no dispute over the fact that this merchandise was shipped in interstate commerce, but the case therefore can be narrowed down to very narrowest limits and the question for this jury to decide is a single question: Is this product misleading? Now the labeling of a cosmetic which contains two or more ingredients may or may not be misleading by reason of the designation of such cosmetic and such labeling by a name which includes or suggests the name of one or more but not all of such ingredients. The fact that Quinine was mentioned on the name of this product is just one of the many features which this jury must take into consideration along with all of the other evidence to determine whether or not the label on it is misleading.

In a prosecution under the Food and Drugs Act intent is not a necessary element of the product. It makes no difference whether a person intends to violate the Act or whether he has got bad intentions. It is a crime under the law for any person to ship a product in interstate commerce which violates the Act.

*[Effect of Long Usage of Name]*

This matter which the jury has to decide is not entirely a new question. The Courts of our country have held that through long usage of a name that that name some times acquires a secondary meaning, for example, the word "Coca-Cola" the Courts have upheld is not deceptive or misleading even though the product contains no coca and very little cola. The name "Coca-Cola" has acquired a secondary meaning, the product, a drink or beverage itself rather than the ingredients suggested by its name.

So, therefore, you can say that a product might be in violation of the Food and Drugs Act because of a misleading name in the early period of its sales, whereas that same product after many, many years of use may no longer be in violation of the Act, if because of that long usage the public has come to understand what the name signifies, and if the public believes it and interprets it to mean a product, a drink such as "Coca-Cola" rather than designating by the ingredients, so much coca and so much cola. The defendant here contends that because of this long usage of this name: "Eau de Quinine" that when the defendant contends that now because of this long usage, when the public buys Eau de Quinine, it is buying a well known hair preparation or tonic by that name and that



*U. S. v. Two Articles of Devices, etc., Tox Eliminator*

the public is not buying a preparation which the public believes to contain a substantial or consequential amount of a drug known as "quinine" or any amount of "quinine." A further example of this principle might be well illustrated by the name: "milk" so far as "Milk of Magnesia" is concerned, or soda in soda water, and as one Court has said that it is not very reasonable to believe that the use of the word: "Eskimo Pie" leads the people to believe that it is a pie made by Eskimos, or is a formula obtained from the Eskimos. That by long usage of the name it signifies a product, rather than a product having certain ingredients in it.

## [Conclusion]

Now, ladies and gentlemen, I have tried to outline to you the respective contentions of parties. The Government says that it is a label which is misleading,—it says that it is misleading because the label represents to the public that it has a consequential amount of quinine in the product, where the Government says that it doesn't have a substantial amount of quinine and that because of that people are likely, the public are likely to purchase it believing that they are getting something that has some medicinal value to their hair or to their scalp, and I might say that there is another matter that is not in dispute. The evidence shows that the drug "quinine" is a drug used primarily for the cure of malaria and that the drug "quinine" has no value whatsoever to the

scalp or to the hair in a hair tonic.

For some reason that name was put in there some years ago and it has continued all down through the years and it is still in that name. The defendant's position I have told you.—The defendant contends that because of the long usage of this name that it is sold to the public, and the public is not misled in believing that it contains so much quinine. The defendant takes the position that the public doesn't care how much quinine is in there and doesn't buy it with any view as to how much quinine is in this product.

Yesterday a statement was made by the [Government's] counsel, to the effect that if anywhere in these United States, regardless of a person's intelligence or literacy, if anywhere there may be a man or woman who might be misled by this name, "Eau de Quinine," that that would probably be a violation of this Act. I want to correct that because I don't think that the statement correctly states the law. The test is whether or not the public is misled or likely to be misled by this name. The goods are misbranded if they bear any statement which would deceive or mislead any purchasers who are of normal capacity and use that capacity in a common sense way.—That is the test and whether there may be any or few so deceived is not material.

[On January 23, 1947, the jury returned a verdict of not guilty.]

**THE UNITED STATES OF AMERICA, LIBELANT, v. TWO  
ARTICLES OF DEVICE INTENDED FOR USE AS A  
COLONIC IRRIGATOR Bearing on Their Nameplate  
The Designation "Tox Eliminator," Respondent,  
Dr. J. C. Rabourn and Dr. Ada Rabourn,  
Claimants<sup>1</sup>**

United States District Court for the Eastern District of Oklahoma.

No. 2343 Civil. February 14, 1949.

Seizure proceedings were instituted against devices known as "Tox Eliminators," on the ground that they were misbranded. The distributor had forwarded by mail from California to its agent in Oklahoma pamphlets and a letter describing the therapeutic effects of the machines. This literature was reproduced by the agent and distributed in Oklahoma, to which the machines had been shipped in interstate commerce. The court concluded that the literature had accompanied the devices in interstate commerce so as to constitute labeling under the Act.

Sections 201 (m), 304 (a), 502 (a), Federal Food, Drug, and Cosmetic Act.

<sup>1</sup> These findings properly belong in the "Seizure Cases" division of this book, but were

issued after that division had gone to press.—Author.



**Federal Food, Drug, and Cosmetic Act**  
*U. S. v. Two Articles of Devices, etc., Tox Eliminator*

Inasmuch as the only labels attached to the devices were name plates bearing the name of the device and the name and address of its distributor, the court concluded that the device was misbranded because the wording on it did not include all the claims for the curing or treatment set out in the advertising literature.

Sections 304 (a), 502 (f), Federal Food, Drug, and Cosmetic Act.

### Findings of Fact and Conclusions of Law

#### *Parties and Jurisdiction*

BOWER BROADDUE, District Judge: 1. The United States brings this action on libel of information for confiscation of two devices manufactured and sold for use as colonic irrigators, under the name of Tox Eliminator. The devices were shipped in interstate commerce from the manufacturer, Tox Eliminator Company in Glendale, California, to the claimants, Dr. J. C. Rabourn and Dr. Ada Rabourn, in Poteau, Oklahoma, within the Eastern District of Oklahoma, where the devices were seized. The articles are alleged to have been misbranded within the provisions of section 301 of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C.A. 331.) This court has jurisdiction. 21 U.S.C.A. 334; 28 U.S.C.A. (Sept. 1, 1948) sec. 1356.

#### *The Tox Eliminator and the Labeling Accompanying Such Devices in Interstate Commerce*

2. The Tox Eliminator is a device consisting of certain pipes, tubes, faucets and accessories offered for sale and sold to be used as a colonic irrigator and providing for controlled irrigation of the colon by water. The device was manufactured and sold by the Tox Eliminator Company of Glendale, California. The agent of the company in Oklahoma was one Mr. Fred McCabe.

3. The company had forwarded by mail from Glendale to McCabe in Oklahoma two pamphlets entitled "The Magic Power of Water" and "The Modern Scientific Drugless Way to Health," and a letter to be used as a circular letter, addressed to "My dear friend." These pamphlets advertising the Tox Eliminator contained representations as to its curative power. McCabe made a sale of one of the devices to a doctor in Sulphur shortly before the sale of the Tox Eliminators here considered. Using the original pamphlets and letter that he had received from California he had identical printed copies thereof made in

Shawnee, the only change being the name of the doctor, and these were used and distributed in connection with the Sulphur sale.

4. Two of the devices were sold by McCabe in September of 1946 to the Rabourns, the claimants in this case. The devices were thereafter shipped in interstate commerce from Louisville, Kentucky, to which city they had been shipped from Glendale, California, and stored, to Poteau, Oklahoma, in December of 1946 and delivered to the Rabourns. At the time of the sale it was agreed as a part of the contract of sale that McCabe would conduct a scheme of advertisement and promotion of the devices by causing the pamphlets and letters, in the form furnished to McCabe by the company and heretofore identified, to be mailed to a list of prospective patients in the vicinity of Poteau, Oklahoma, to induce them to seek treatments by the use of the devices in the office of the claimants. The literature was examined by the Rabourns and, upon their approval, copies of the pamphlets and the circular letter received by McCabe from the company in Glendale, or copies of the former Shawnee printing of the same literature were reproduced or printed in Shawnee and mailed by a local mailing agency to some two thousand persons of a prepared list of prospective patients. The Rabourns reimbursed McCabe for this expense as agreed in the sales contract.

5. The literature mailed made claims as to the effectiveness of the machine in the cure or relief of many of the ills that effect the human body. Though it is admitted by the claimants that these claims are false, they assert that the government may not successfully proceed in this libel of information because the literature in question under the facts was not a labeling of the devices as it was not (1) upon the device sold and shipped in interstate commerce or (2) did not accompany such device within the meaning of the Federal Food, Drug and Cosmetic Act. (21 U.S.C.A. Sec. 321 *et seq.*)



*U. S. v. Two Articles of Devices, etc., Tox Eliminator**Conclusions of Law*

A. The Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. Sec. 321, *et seq.*) is primarily for the protection of the public and should receive a liberal construction. *United States v. Dotterweich*, 320 U. S. 277; *Pasadena Research Laboratories, Inc. v. United States*, 9 Cir., 169 F. 2d 375; *Arner Co. v. United States*, 1 Cir., 142 F. 2d 730; *United States v. Research Laboratories*, 9 Cir., 126 F. 2d 42.

B. As the literature used makes false claims of the curative value and effectiveness of the device, it is a misbranding if such literature be considered to be a part of the labeling under the provisions of the statute. 21 U. S. C. A., Sec. 352 (a); *United States v. One Device*, 10 Cir., 160 F. 2d 194. "Labeling" means all labels and other written, printed or graphic matter upon any article or its container or wrapper; or accompanying such article. 21 U. S. C. A., Sec. 321 (m). The circular and pamphlets not being upon or attached to the devices or their containers or wrappers, the inquiry is whether such matter accompanied the devices within the purview of the section. The phrase "accompanying such article" is not restricted to "labeling" that is on the article of package forwarded in interstate commerce. As used in the Act, "accompanying" described the relationship between the article and its labeling. The accompaniment is one of commercial association. An article or device is accompanied by labeling when the labeling supplements or explains the use of the article. *Kordel v. United States* (not officially reported) No. 30, October Term, Nov. 22, 1948, *United States v. Kordel*, 7 Cir., 164 F. 2d 913; *United States v. Kordel*, D. C. N. D. Ill., 66 F. Supp. 538; *United States v. Lee*, 7 Cir., 131 F. 2d 464; *United States v. Paddock*, D. C. W. D. Mo., 68 F. Supp. 407; *United States v. 7 Jugs, etc.*, D. C. Minn., 53 F. Supp. 746.

Here both the literature and the device originated in California; the device being shipped in interstate commerce and the original or copy of the literature being sent from California to Oklahoma by mail to be subsequently used as the pattern or copy for the pamphlets and circulars sent out pursuant to the sales agreement. It was "an accompanying" within the meaning of the Act. To hold otherwise would be to permit an escape from the purpose of the Act by the plainest sort of subterfuge.

C. Nor does the fact that the literature was distributed for advertising purposes

prevent it from being "labeling" as defined by the Act. *U. S. v. Kordel*, 7 Cir., *supra*; *United States v. Paddock*, D. C. W. D. Mo., 67 F. Supp. 819.

*The Sufficiency of the Labeling*

6. The only labels attached to the devices are the respective name plates, each with the words "Tox Eliminator, Tox Eliminator Company, Inc., Glendale, California, Serial No. ———." The government contends that should the circulars be held not to be labeling within the concept of the Federal Food, Drug, and Cosmetic Act then the devices are misbranded because of the insufficiency of the labeling.

7. As a part of the sales agreement it was agreed that soon after the delivery of the machines the company would conduct a clinic called a "health clinic" to introduce the machines to the public. A licensed chiropractor of California, not licensed to practice the healing art in Oklahoma, was sent from California office of the Tox Eliminator Company to demonstrate the device and assist in the holding of the clinic. He gave a short course of instruction to the Rabourns so they might understand the operation of the devices and he assisted in the giving of treatments with the devices. Following this clinic and instruction, like treatments were given under the supervision of either of the Rabourns in their offices.

*Conclusions of Law*

D. A device shall be deemed to be misbranded unless its labeling bears adequate directions for use provided where such requirement as applied to such device is not necessary for the protection of the public health the Administrator shall promulgate regulations exempting such device from the requirement. 21 U. S. C. A., Sec. 352 (f) (1).

E. The Federal Security Administrator is authorized to promulgate regulations for the efficient enforcement of the law (21 U. S. C. A., Sec. 371 (a)); and such regulations may be interpretive of the statute in so far as they do not conflict with or add to the provisions of the law. *United States v. Antikamnia Chemical Co.*, 231 U. S. 654, 666; *Arner v. U. S.*, 1 Cir., 142 F. 2d 730, certiorari denied 323 U. S. 730. Under such authority the Administrator has adopted regulations not inconsistent with his powers providing that directions for use may be inadequate by reason of omission in whole or in part of incorrect specifications of directions for use in all conditions for which



devices are prescribed, recommended or suggested in the labeling or advertising disseminated or sponsored by its manufacturer or packer, or in such other conditions as said device is commonly or effectively used. 21 Code of Federal Regulations, Cum. Supp., Sec. 2.106 (a) (1). The label on the device containing the words "Tox Eliminator" standing alone is not a misbranding as the device tends to remove toxins (*U. S. v. One Device, supra*) but in the light of Regulations Sec. 2.106 (a) (1) the branding is inadequate because the words on the devices do not include all the claims for the curing or treatment set out in the advertising circulars. *United States v. 150 Packages Bush Mulso Tablets*, Civil No. 4415, D. C. E. D. Mo. (not officially reported); *United States v. 516 Cases Nue-Ovo*, D. C. S. D. Cal. No. 7418-C, 1948 (not officially reported). The devices were misbranded unless exempted by some other provision of the law or regulations made pursuant thereto.

8. As to many of the diseases and conditions referred to in the circulars the devices are of no benefit as a cure and afford no relief. To such an extent the claims and implications of the circulars are false and misleading.

#### *Conclusion of Law*

F. Exempted from the requirement of Sec. 352 (f) (1) of the statute (except as otherwise provided by paragraph (h) and (i) of Sec. 2.106 of the regulation) is the delivery or shipment of a device complying with certain conditions, among which conditions are that adequate information for the use of the device by a physician is readily available (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (b) (5) (i); and that the shipment or delivery complies with all the conditions set forth in paragraphs (b) (3) of such regulatory section and is made to a physician to be dispensed by or under the direction of a physician in his professional practice (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (e)). The effect of the regulation in application to the facts of this case is that the shipment or delivery of the device is exempted from

Sec. 352 (f) (1) of the statute if adequate information for the use of the device by a physician is readily available; and it is made to a physician to be dispensed by or under the direction of a physician. That the devices were delivered to physicians to be dispensed under the direction of such physicians is clear. There remains the question of whether adequate information for the use of the device by a physician is readily available. The adequate information required relates to the use of the machine in the treatment of the diseases and conditions for which it is intended to be used, as set forth in the circulars. Such adequate information must be readily available. While it may be possible that harm or injury might not result in certain instances from use of the devices under the supervision of chiropractors, the exemption from the requirement of the statute may not be allowed for that reason standing alone. It is within the spirit and intent of the statute that the public be protected from fraudulent representations of the curative or beneficial result to be secured from the use of a device; and the words in the exemption of the regulation that "adequate information for the use of the device by a physician be readily available" embraces the concept of truthful and adequate information of its use to bring about probable cure of or some relief from the diseases and conditions contained in the circulars and advertisements. As many of the claims of the circulars have no basis in fact, adequate information for their use may not be considered as readily available. Were it otherwise the probable harm from the use of the devices for conditions or diseases or the delay in securing relief by other means might find justification never contemplated but intended to be denied by the broad purposes of the statute.

Judgment of condemnation will be entered as of the date of the filing of these findings of fact and conclusions of law, this the 14th day of February, 1949, and the machines will be delivered to the proper authorities for disposition as provided by law.



*U. S. v. Various Quantities of "Instant Alberty Food," etc.*

UNITED STATES OF AMERICA v. VARIOUS QUANTITIES OF ARTICLES OF DRUG LABELED IN PART: "Instant Alberty Food \* \* \*," "Alberty's Food \* \* \* Regular \* \* \*," "Alberty Vitamin B. Complex Tablets with High-Potency B I \* \* \*," "Alberty's Vio-Min Vitamin-Mineral Tablets \* \* \*," "Alberty Garlic Vegetable Oil Perles \* \* \*," "Alberty's Lebara Pellets Homeopathic \* \* \*," "Alberty's Lebara No. 2 Pellets \* \* \*," "Alberty's Oxorin Tablets \* \* \*," "Tablets Pandora \* \* \*," "Alberty's Phosphate Pellets \* \* \*," "Alberty's Phloxo B Tablets \* \* \*," "Recal Tablets \* \* \*," "Alberty Riol Tablets \* \* \*," "Alberty's Sabinol (pellets) \* \* \*," "Alberty Special Formula Tablets \* \* \*," "Alberty's Vegetable Compound Capsules \* \* \*," "Alberty's Vitamin A (perles) (High Potency) Shark Liver Oil \* \* \*," "Alberty's Vitamin B I with Supplementary Amounts of the Other B-Complex Factors \* \* \*," and "Wheat Germ Oil \* \* \* Perles \* \* \*"¹

United States District Court for the District of Columbia. District Court No. 3188.  
March 25, 1949. 83 F. Supp. 882.

Seizure proceedings were instituted against articles of drug on the ground that certain of them were misbranded under Section 502(f)(1) because their labeling did not contain a statement listing the diseases as to which they were claimed to possess therapeutic value in advertising material, and that others were misbranded because their labeling contained no directions for use other than a designated quantity and frequency of dosage. The government moved to strike claimant's defenses that the section does not require that the labeling of a drug state the diseases for which the drug, when used as directed, will be effective, and that the labeling prescribed maximum quantity and dosage which satisfied the requirements of the section. The court declared that the Act requires that all drugs be labeled in such fashion that the consumer is given all information reasonably necessary for the intelligent use of the drug in self-medication.

Sections 304(a), 502(f), Federal Food, Drug, and Cosmetic Act.

The words "adequate directions for use" necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. No drug can be said to contain in its labeling adequate directions for its use unless every ailment for which it is, through any means, held out as an efficacious remedy, be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment.

Sections 304(a), 502(f), Federal Food, Drug, and Cosmetic Act.

The clear meaning of the Federal Security Administrator, in the interpretative regulation issued under Section 502(f)(1), is that not only the dosage, but the diseases for which such dosage is recommended or advertised, must appear in the labeling if the labeling is to be held to bear adequate directions for use.

Sections 304(a), 502(f), Federal Food, Drug, and Cosmetic Act.

It is well-settled that the action of either the Food and Drug Administration relative to misbranding, or the Federal Trade Commission relative to false advertising, is not the exclusive remedy afforded to the government in a case where both misbranding and false advertising are present.

Sections 304(a), 502(a), 502(f), Federal Food, Drug, and Cosmetic Act.

Vincent A. Kleinfeld, Department of Justice, Washington, D. C., for libellant.

Glen E. Weston, 1302 18th Street, N. W., Washington, D. C., for claimant.

¹ This opinion properly belongs in the "Seizure Cases" portion of this book, but was rendered after that portion had gone to press. —Author.



BEN MOORE, District Judge: On October 19, 1948, the government filed a libel against various quantities of articles alleged to be articles of drug and to have been shipped in interstate commerce by Alberty Food Products, a co-partnership. Various dates of shipment are alleged, beginning March 26, 1947, and ending November 10, 1947. The libel charges misbranding, within the meaning of Section 352(f)(1) of the Federal Food, Drug, and Cosmetic Act. (21 U. S. C. A. 301 *et seq.*) Different bases for the allegations of misbranding are alleged with reference to different shipments. They fall into three groups. As to one group of shipments, it is alleged that they were misbranded because they did not contain in the labeling a statement listing various diseases and ailments of the human body as to which they were claimed to possess therapeutic value, in two booklets disseminated by the manufacturer, packer and distributor, denominated respectively "Health Mysteries" and "Dynamic Digest." Another group is alleged to be misbranded for lack of the same information in the labeling, but with reference to "Dynamic Digest" alone. The third group is alleged to be misbranded, not only because its labeling contains no reference to the diseases for which claims are made in "Health Mysteries" and "Dynamic Digest," but also because the labeling contains no directions for use other than a designated quantity and frequency of dosage.

Alberty Food Products on December 2, 1948, filed its answer to the libel, setting up, among other defenses, (A) that Section 352(f)(1) of the Act does not sustain the allegations of the libel for the reason, as claimant avers, that the provision that the labeling contain "adequate directions for use" does not require that the labeling of a drug state the diseases or conditions of the body for which the drug when used as directed will be effective, nor does it require that the labeling of a drug state each of the diseases and conditions of the body for which the drug is advertised as a therapeutic treatment; (B) that the dissemination of the booklets "Health Mysteries" and "Dynamic Digest" has been abandoned by the claimant following cease and desist orders of the Federal Trade Commission heretofore issued against the claimant on the ground that the booklets contain false advertising; (C) that the labeling upon each of the articles prescribes maximum quantity and dosage, and therefore satisfies the re-

quirements of Section 352(f)(1) of the Act, and (D) that the booklet entitled "Dynamic Digest" was not disseminated prior to August 15, 1947, whereas some of the articles alleged to be misbranded for lack of information in the labeling about diseases and ailments concerning which claims are made in "Dynamic Digest" were alleged to have been shipped in interstate commerce prior to that date.

The government has moved to strike the above defenses from the answer on the ground that they are insufficient in law, and on the further ground as to some of them that they are immaterial.

[*Relevant Portions of the Act*]

The relevant portions of the Act, together with the interpretive regulation with reference thereto issued by the Commissioner of Food and Drugs on December 22, 1939, as amended April 10, 1941, are as follows:

Section 352:

"A drug or device shall be deemed to be misbranded . . .

"(f) Unless its labeling bears (1) adequate directions for use; . . ."

Section 334:

"(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . ."

21 C.F.R. Cum. Supp. Section 2.106:

"(a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:

"(1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used; . . ."

[*Congressional Intent*]

It is clear from the terms of the Food, Drug and Cosmetic Act, as well as from its legislative history, that Congress intended, insofar as the Act relates to drugs, to provide effective safeguards for the pub-



lic in their use of such articles, by requiring that all drugs shipped in interstate commerce be labeled in such fashion that the consumer thereof shall be given all information reasonably necessary for the intelligent use of the drug in self-medication. H. R. 2139, 75th Cong., 3 Sess. p. 8.

*[Self-Medication May Endanger Health]*

It is obvious that in the use of drugs for self-medication the health of the consumer may be endangered in any of three ways: First, if the drug is misbranded either by omission from the labeling of a statement of its ingredients, or by false statements in the labeling with reference to the contents of the package, or with reference to the efficacy of the drug in the treatment of certain diseases; secondly, if the drug is placed on the market with no mention in the labeling of any disease or ailment for which the manufacturer intends it to be used as a cure or palliative, while at the same time the manufacturer falsely advertises it to the public through other means as having therapeutic value in certain diseases; and, thirdly, if the labeling mentions some diseases or ailments for which the drug is claimed to be a remedy, while the manufacturer falsely advertises to the public by other means that it is a remedy for other and different diseases and ailments. The peril to public health from the first of these means is apparent from its mere statement, and Congress has provided protection against the danger in Section 352(a) of the Act. It is perhaps not so clearly apparent from the other two means. Nevertheless the danger therein is real and substantial. Where no diseases or ailments whatever are mentioned in the label, if the consumer who purchases the product is one who is not aware of the advertised claims he is left to speculate without guide as to the diseases or conditions for which it is intended to be used, and therefore may use it for some condition in which it is neither effective nor intended to be so, but may be harmful. If the consumer is aware of the advertising, he is led to purchase the drug for self-medication in some disease or condition for which it is not effective, and may be hurtful. In the third situation, a consumer who has knowledge of the advertiser's claims may purchase the drug for use, not for an ailment specified in the labeling, but in some disease or condition for which the advertiser falsely claims it is efficacious, though not mentioned in the

labeling; and in such case, if the advertiser's advice be followed, the result is the same as in the second situation. A purchaser is led into a form of self-medication which is of no benefit to him, which may be directly harmful, and which is further deleterious to his health because of the fact that it deters or prevents him from seeking other means of relief.

The section of the statute under consideration must be construed in the light of the underlying Congressional purpose, and so as to give effect to the Act as a whole, if a reasonable construction can be arrived at which may accomplish that end.

*[Purpose Served by Use of Drugs]*

The words, "adequate directions for use," necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment. See the following unreported cases, cited in the government's brief: *United States v. 150 pkgs. . . . Bush Mulso Tablets*, (E. D. Mo.) No. 4415, CCH Food Drug Cosmetic Law Reports ¶ 7059; *United States v. 516 cases . . . Nuc-Ovo*, (S. D. Col.) No. 7418, CCH Food Drug Cosmetic Law Reports ¶ 7091.

It may be that compliance with this requirement, thus freeing the shipper from any liability under Section 352(f)(1), would result in the drug being misbranded under Section 352(a) of the Act; and doubtless this is the precise result which was intended in those cases where false and misleading advertising claims are made which are omitted from the labeling.

Any other construction of Section 352(f)(1) would provide the manufacturer and shipper with a convenient loophole through which he could evade the Act with resulting danger to public health. He need only include in the labeling either dosage directions alone, or with the addition of one or more bodily diseases or ailments for



which he claims the drug is efficacious, and by a contemporaneous advertising campaign lead the public to believe that the drug is a remedy for a multitude of ailments. In such cases, if claimant's first and third defenses be good, there is no section of the Act which protects the public against the resulting harm.

I am not impressed by the argument of counsel for claimant that the administrative interpretation hereinbefore set out sustains his construction of Section 352(f)(1). Keeping in mind the Congressional intent, I am of opinion that the clear meaning of the Administrator in this interpretive regulation is that not only the dosage, but the disease or diseases for which such dosage is recommended or advertised, must appear in the labeling if the labeling is to be held to bear adequate directions for use. This conclusion finds support in the unreported case of *United States v. Colgrove*, (S.D. Cal.) cited in the government's brief as No. 5992, CCH *Food Drug Cosmetic Law Reports* ¶ 7046, in which case the District Court granted an injunction restraining defendants from introducing into interstate commerce any product without a label bearing adequate directions for use of such product in the treatment of all ills for which it was advertised, which directions were to include the dosage to be taken in each of such conditions.

Paragraphs (A) and (B) of claimant's first defense in the answer to the libel, and the third defense therein, will therefore be stricken as insufficient defenses.

[*Drugs Shipped Prior to Booklet*]

It will next be considered whether the alleged fact that the booklet, "Dynamic Digest," was not disseminated prior to August 15, 1947, if true, is a defense to the allegation that certain articles of drug which were shipped prior to that date were misbranded for lack of inclusion in the labeling of the names of the diseases and ailments for which they were recommended for use in "Dynamic Digest," together with directions for their use in such ailments. All but five of the articles of drug mentioned in the libel were advertised in both "Health Mysteries" and "Dynamic Digest," with substantially the same recommendations and representations with respect to their remedial and curative qualities. One of the five shipments as to which the allegations are based solely on claims made in "Dynamic Digest" was made after August

15, 1947. As to another of the five, the allegation of misbranding is based not only on claims made in "Dynamic Digest," but also on omission from the labeling of any directions for use other than mere prescription of the quantity and frequency of dosage. Therefore, the words "but avers that 'Dynamic Digest' was not disseminated by it prior to August 15, 1947," appearing in Paragraphs 21, 22, 23, 27, 29, 33, 34, 35, 36, 38, 39, 41 and 42 of the fourth defense will be stricken as immaterial.

This leaves for consideration three articles of drug advertised only in "Dynamic Digest," of which some shipments were made prior to August 15, 1947, with respect to which the sole basis of the libel is that claims of therapeutic qualities as to certain diseases were made in "Dynamic Digest."

It is my opinion that the drugs in these particular shipments could not be said to be misbranded under the terms of Section 352(f)(1) by reason of omission from the labeling of those diseases and ailments for which the drugs had not been held out in any way to the public as cures or palliatives prior to the respective dates of shipment. Therefore, I will overrule the motion to strike the words "but avers that 'Dynamic Digest' was not disseminated by it prior to August 15, 1947," appearing in Paragraphs 25, 31 and 43, of the fourth defense, insofar as they relate to those shipments of the three articles of drug last referred to made prior to August 15, 1947. Of course, the government may still prevail in its charge that these drugs were misbranded, if it can prove that it was the intention of the shipper at the time of shipment to make the claims for them which were afterwards made in "Dynamic Digest"; but this proof cannot rest alone on the fact that "Dynamic Digest" was subsequently disseminated.

[*Abandonment of Booklets*]

Finally, with reference to the second defense, namely, that dissemination of the booklets "Health Mysteries" and "Dynamic Digest" has been abandoned by the claimant: it does not appear from any of the pleadings that the booklets are alleged to have been abandoned prior to the shipping date of any of the shipments which were seized. Their abandonment after shipments were made could constitute no defense to the allegation of misbranding, since under the Act misbranded drugs may be seized at any time after they are shipped in interstate commerce. 21 U.S.C.A. 334. There-



fore, the motion to strike the second defence will be sustained as the pleadings now stand. However, I believe that if the answer were amended to show that the abandonment of dissemination of the booklets took place before the date of some or all the shipments, this would be a good defence, at least conditionally, as to those shipments which were subsequent to the abandonment. I say conditionally, because it is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named in the booklets, that the abandonment can be said to be effective as a defense. The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases mentioned in the booklets; but in the absence of such proof, it is my opinion that the abandonment would warrant the inference that there was no intent to misbrand as to drugs shipped thereafter.

[*Concurrent Jurisdiction of Food and Drug Administration and FTC*]

One of the arguments advanced by claimant is that since the Federal Trade

Commission has been given authority by Congress to prevent false advertising, whereas such authority has been denied to the Food and Drug Administration, it should be held that the Federal Trade Commission is the only agency of government which can operate in this field. But it is well settled that the action of either of these agencies—that of the Food and Drug Administration relative to misbranding, and that of the Federal Trade Commission relative to false advertising—is not the exclusive remedy afforded to the government in a case where both misbranding and false advertising are present. In other words, the fact that the government may seize an article because it is misbranded does not prevent the Federal Trade Commission from issuing a cease and desist order with reference to false advertising concerning that article; and conversely, the issuance of a cease and desist order does not prevent the government from proceeding against the article because of the misbranding. *United States v. 5 Cases of Capon Springs Water*, (C.C.A. 2, 1946) 156 F. (2d) 493; *United States v. Research Laboratories*, (C.C.A. 10, 1942) 126 F. (2d) 42, cert. denied 317 U.S. 656.

An order may be entered in accordance with this opinion.

---

**LAFAYETTE M. GRAY (ALSO KNOWN AS L. M. GRAY),  
APPELLANT v. UNITED STATES OF AMERICA,  
APPELLEE<sup>1</sup>**

United States Court of Appeals for the Eighth Circuit. No. 13,773.  
April 18, 1949. Modified June 6, 1949

Each of two counts of a criminal information filed against the defendant charged him with having introduced into interstate commerce a drug which was misbranded in several particulars. The Court of Appeals found no error in the ruling of the trial court that the charge in each count was single and not duplicitous in that the offence charged in each count was the introducing and delivering for shipment in interstate commerce of a misbranded article, in violation of Section 301(a).

Sections 301(a), 303(a), 502(a), 502(e), 502(f), Federal Food, Drug, and Cosmetic Act.

A form of verdict had been submitted to the jury which required the jury to make special declarations by use of the words "guilty" or "not guilty" in respect to each of the particulars of the misbranding charged in each count. The Court of Appeals declared that this procedure constituted error; and that in criminal trials the practice had been settled to charge but one crime in one

---

<sup>1</sup> This opinion properly belongs in the "Criminal Cases" portion of this book, but

was rendered after that portion had gone to press.—Author.



count, to accept but one general plea to it, and to call upon the jury to make but one general response, guilty or not guilty.

Section 301(a), 303(a), 502(a), 502(e), 502(f), Federal Food, Drug, and Cosmetic Act.

The court declared that the verdicts, which purported to find the defendant guilty of introducing a drug into interstate commerce which was misbranded because its "label" was false and misleading, were fatally defective, because the information charged him with the introduction into interstate commerce of a drug whose "labeling" was false and misleading.

Sections 301(a), 303(a), 502(a), 502(e), 502(f), Federal Food, Drug, and Cosmetic Act.

The court held that the defendant had been put in jeopardy; that the jury had been discharged without having rendered verdicts of guilty responding to the charges; and that the defendant was entitled, therefore, to have the judgment against him avoided and to have a new trial.

Sections 301(a), 303(a), 502(a), 502(e), 502(f), Federal Food, Drug, and Cosmetic Act.

Mr. C. A. Taney, Jr. (Mr. Leonard L. Kalish was with him on the brief), for appellant.

Mr. Clifford F. Hansen, Assistant U. S. Attorney (Mr. Alexander M. Campbell, Assistant Attorney General; Mr. John W. Graff, U. S. Attorney; Mr. Vincent A. Kleinfeld, Attorney, Department of Justice, and Mr. Bernard D. Levinson, Attorney, Federal Security Agency, were with him on the brief), for appellee.

Before GARDNER, Chief Judge, and WOODROUGH and THOMAS, Circuit Judges.

WOODROUGH, Circuit Judge, delivered the opinion of the Court. The appellant was convicted and sentenced to pay a fine of one thousand dollars and costs for introducing into interstate commerce a certain drug called Powdr-X contained in packages and misbranded, in violation of the Federal Food, Drug, and Cosmetic Act § 301(a) *et seq.*, 21 U.S.C.A. 331(a) *et seq.* The information against him contained four counts but the jury found him not guilty on count 2, and count 4 was dismissed during the trial. This judgment from which he appeals was entered upon the jury verdicts on the remaining counts of the information numbered one and three. Each of these counts was predicated upon one of the two shipments of packages of the drug made by appellant at Minneapolis, Minnesota; one shipment on December 6, 1945 to Mrs. H. Feltenberger at Culver City, Calif. (first count), and the other on March 23, 1946 to Ira J. Evans at North El Monte, Calif. (third count). The charge was to the effect that in each of the shipments the drug was misbranded in violation of the Act; (1) that the label upon each of the immediate containers was as follows:

"POWDR  
X  
Net Weight 8 oz.  
CONTENTS  
Silicon Dioxide, Aluminum Oxide,  
Ferric Oxide, Calcium Oxide,  
Magnesium Oxide, Sodium Oxide.  
L. M. Gray, National Distributor  
3856 Chicago Avenue  
Minneapolis, Minn.  
Phone Colfax 8295."

(2) that the appellant accompanied each shipment with a letter intended to be used together with the drug and constituting a labeling thereof, which letter he mailed to the consignee on the same day he made the shipment. In one of the letters it was stated that the drug was "splendid for almost any infection, abrasion or ulcers" (first count), and in the other that "We have good reason for expecting Powdr X to correct ulcers of the stomach \* \* \*". "Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days," which statements were false and misleading and in truth said drug would not be efficacious as stated; (3) that the drug was not designated by a name recognized in an official compendium and its



label failed to bear the common or usual name of the drug, to wit, pumice; (4)<sup>1</sup> the labeling failed to bear adequate directions for use, to-wit, there were no directions for use.

*[Motion To Dismiss Information]*

Before entering his plea appellant moved to dismiss the information on the ground that each of the counts was duplicitous in that each attempted to charge more than one offense denounced by the Act, because each count<sup>2</sup> charged against him conduct alleged to be in violation of 21 U.S.C.A. 352(a)<sup>3</sup> and conduct alleged to be in violation of 21 U.S.C.A. 352(e)<sup>4</sup> and conduct alleged to be in violation of 21 U.S.C.A. 352(f).<sup>5</sup>

It was argued for the motion and is reiterated here that these three kinds of conduct connected with the shipment of drugs in interstate commerce, to-wit, (1) accompanying the shipment with a letter containing false statements; (2) failing to put the true name of the drug on its "label," and (3) failing to include directions for use in its "labeling," should be deemed separate offenses and pleaded in separate counts under 18 U.S.C.A. 557 and Rule 8(a) of F.R.C.P. It is stressed that the Act makes clear and positive distinction between conduct in respect to what the Act defines as the "label" on the package of the drug and in respect to what it defines as the "labeling" of the drug. 21 U.S.C.A. § 321(k) provides that "the term 'label' means a display of written, printed or graphic matter upon the immediate container of any article; \* \* \*," and 21 U.S.C.A. § 321(m) says that "The term 'labeling' means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The Act makes "labeling" the broadly inclusive term and "label" is narrowly confined to what is put on the immediate container. It is contended that writing and mailing a letter containing false statements about the drug is conduct so different in kind from failing to put required matter in its label or failing to put required instructions for use in either the

letter or the label that the inclusion of charges of the three sorts of misconduct in each count made each count duplicitous.

*[Conclusions of Trial Court]*

The trial court after consideration of the motion and argument, concluded that the charge in each count was single and not duplicitous in that the offense charged in each count was the introducing and delivering for shipment in interstate commerce of a misbranded article, in violation of 21 U.S.C.A. § 331(a), which prohibits the introduction or delivery for introduction into interstate commerce of "any \* \* \* drug that is \* \* \* misbranded," under penalties provided in § 333(a). It deemed the several acts and omissions charged against appellant to be specifications of the ways in which that offense was committed by him. We find no error in that ruling.

But the court recognized that the offense in each count might be established under the information by proof of either one or all of the ways in which misbranding was charged to have been accomplished and it suggested to the prosecutor to amend the information by adding to it at the foot of each count the following:

"It being the intent and purpose of the plaintiff to charge hereunder only one interstate shipment and offense under the Food, Drug and Cosmetic Act."

The amendment having been made the motion was treated as being directed against the amended information and was denied, a plea of not guilty as to each count was entered and the trial proceeded before the court and jury over a period of 16 days. It was not disputed that the appellant had made the two shipments of the drug, each including a number of packages of the Powdr-X produced by grinding up a certain mineral substance found in volcanic formation on a ranch property in Colorado, nor that the packages shipped bore the label described in the information, nor that appellant caused the two shipments to be accompanied by the described letters mailed by him to the respective consignees, but the testimony of lay and expert witnesses on

<sup>1</sup> Count three did not include this specification (4) contained in count one.

<sup>2</sup> Except as above noted.

<sup>3</sup> Section 352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

<sup>4</sup> (e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; \* \* \*.

<sup>5</sup> (f) Unless its labeling bears (1) adequate directions for use.



the questions as to what Powdr-X really was and whether or not it was pumice as charged and whether or not it had therapeutic capacities as represented in the letters was very voluminous and contradictory in respect to the inferences to be drawn from it.

[*Forms of Verdict*]

At the conclusion of its instructions to the jury the court delivered to the jury forms of verdict with blank spaces which the jury was directed to fill in with the words "guilty" or "not guilty," according to the findings arrived at. The forms had been prepared by the prosecution and appear not to have been exhibited to appellant's counsel, or discussed before their delivery to the jury. There was one form for each of the three counts submitted to the jury but each form required the jury to make and declare more than one determination of "guilty" or "not guilty" upon each of the three counts submitted to it. Responding to count one, the form filled in by the jury with the words "guilty" and "not guilty" and returned into court as the jury's verdict on that count reads as follows:

"Verdict as to First Count of Information (Feltenberger)

"We, the jury in the above entitled action, find the defendant, as charged in the first count of the Information . . . guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, with a label which was false and misleading; not guilty of misbranding by introducing a drug, to-wit, Powdr-X, in interstate commerce which was not designated solely by a name registered in an official compendium and that its label failed to bear the common name of the drug, to-wit, pumice; not guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, which failed to bear adequate directions for use. (Feltenberger)

"Dated this 27th day of March, 1948

"Richard A. Fancher

"Foreman,"<sup>6</sup>

As shown on the face of this verdict the jury undertook to make special declarations by use of the words "guilty" or "not guilty" in respect to particulars of misbranding described by paraphrases of parts of the information in the verdict-forms but the only matter in respect to which the jury found the appellant guilty was "of misbranding by introducing into interstate commerce a

drug, to-wit, Powdr-X, with a label which was false and misleading." Responding specially to other particulars of the charges paraphrased in the verdict-forms, the jury wrote in the words "not guilty."

The record shows that after the instructed jury had been deliberating for some hours without coming to agreement the prosecuting attorney in the presence of appellant's counsel indicated to the trial judge in chambers that mistakes had been made in the wording of the forms of the verdicts delivered to the jury which they were directed to fill out. The prosecutor used the verdict form applicable to the first count for illustration and pointed out to the court that the wording of the form related the declaration of "guilty" or "not guilty" which the jury might write in the first blank space in the form, to "a label" that was false instead of to "labeling that was false" but there was no formal request or motion to recall the jury and make the correction. There was extended discussion in chambers between counsel on both sides and the judge, but it resulted in no action taken concerning the verdict-forms. The court indicated it was satisfied with the verdict-forms. Later the jury returned into the court requesting further instructions but the matter of the verdict-forms was not then referred to. On the coming in of the verdicts the court entered judgment:

"It is adjudged that defendant has been convicted upon verdicts of guilty of the offense of misbranding by introducing into interstate commerce a drug, to-wit: Powdr-X, with a label which was false and misleading as charged in counts 1 and 3 of the information \* \* \*," and sentence was imposed as stated.

[*Motion for Acquittal by Appellant*]

At the conclusion of all the evidence the appellant had moved for verdict of acquittal and promptly after the verdict had been returned against him he again moved for judgment of acquittal. The motions were denied and he contends here that the rulings were erroneous.

(1) In the first place he contends that in this criminal prosecution there was no power or discretion in the court to require the jury to return verdicts which were in the nature of the special interrogatories and answers thereto which are permissible in civil actions but which have no place in criminal procedure. His position is that a

<sup>6</sup> The form of verdict on count 3 was the same omitting the last not guilty finding.



count in a criminal information must state only one offense; that the only permissible plea to it is guilty or not guilty or *nolo contendere*, and that upon the plea of not guilty the only issue for the jury joined by the charge of the count and the plea is the general issue of "guilty" or "not guilty," and that the jury must be required to respond to that issue by a general verdict. His counsel took timely exception to the action of the court in submitting verdict-forms to the jury requiring multiple responses to each count on the ground that the forms "required or permitted the jury to make a finding of guilty or not guilty three times in respect to count one, twice in respect to count two and twice in respect to count three," and

"there is no authority by statute, by Federal Rules of Criminal Procedure, or by precedent of decision to permit such verdicts to be submitted to the jury for the purpose of returning verdicts in any criminal case; and upon the further ground that it in effect gives the jury an opportunity to arrive at some sort of compromise which they might not arrive at if they were given verdicts which required them to find only once as to each of the three counts whether the defendant is guilty or not guilty."

In the argument here appellant's counsel again asserts that after diligent search he has found "no statute, Rule of Criminal Procedure or precedent of decision" sanctioning the delivery of such a form of verdict to the jury for the purpose of returning their verdict in a criminal case or the requirement that the jury respond three times "guilty" or "not guilty" to one count of a criminal information. The prosecutor cites none and we find none. We think, as stated by the court in *Anderson v. United States*, 273 F. 677, that "it is not the practice of the federal courts in criminal cases to call for special verdicts." c.f. *United States v. Noble*, 155 F.2d 315. And we are constrained to conclude that the delivery of these forms to the jury and the direction to fill them out with several declarations of guilty or not guilty as to each count present an innovation in American criminal practice. It would serve no purpose to review the discussions of the courts and law writers concerning the use of special interrogatory and answer verdicts in civil actions. There are many well known arguments for and against the practice but no one doubts that the question whether it should or should not be followed is a question of due process and is important and far reaching. The vesting of

discretion in the trial court to apply the practice in civil actions ultimately achieved by Rule 49 of the new Rules of Civil Procedure however is no indication of authority to use it in criminal trials. In such trials the practice has been settled time out of mind to charge but one crime in one count, to accept but one general plea to it and to call upon the jury to make but one general response, guilty or not guilty. Such established procedure was obviously departed from here over appellant's objection and it may not be held that such a departure did not affect appellant's substantial right to be tried according to law. It is not the function of the courts subordinate to the Supreme Court to introduce innovations of criminal procedure. The action of the court requiring the special verdicts duly excepted to by the appellant constituted error.

(2) Appellant also contends here, as he did upon his motion for acquittal made after verdict in the trial court, that the verdicts which purport to find him "guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X with a label which was false and misleading" were fatally defective and insufficient to support a judgment of conviction or sentence against him because the information did not charge him with that offense and there was no substantial evidence that he committed it.

The record, considered with the provisions of the Act, has convinced that this contention for appellant is sound and that the verdicts are fatally defective. It is clear that the Act makes it a punishable offense to introduce a drug into interstate commerce "with a label which is false and misleading." 21 U.S.C.A. § 331(a) prohibits such introduction of a drug that is misbranded; 21 U.S.C.A. § 352(a) says that a drug is misbranded if its "labeling" is false or misleading in any particular, and 21 U.S.C.A. § 321 (m) says that "the term 'labeling' means 'all labels'" as well as other things. But in this information the only specification against the label with which the Powdr-X drug was shipped was that the label failed to bear the common or usual name of the drug. Although the label was set out in full in the information, it was not stated that the label was false or misleading and there was no proof that it was. It is beyond argument that a man cannot, under the Fifth and Sixth Amendments, be convicted and sentenced for an offense not charged and not proven against him, and that is the situation in which this appellant



stands upon the record before us. As succinctly stated by the Supreme Court a hundred and fifty years ago, "A verdict is bad if it varies from the issue in a substantial matter," *Patterson v. United States*, 2 Wheaton 221.

[Government Support of Judgment]

It is argued for the government in support of the judgment that we may regard the opening words of the verdicts, "We, the jury find the defendant as charged in the first count of the information guilty of misbranding," to be a general verdict of guilty on the first count and may treat the remaining parts of the verdicts as surplusage. That is to say we should treat as surplusage not only the jury's specific finding that defendant was guilty of the certain clearly stated offense denounced by the Act in respect to "a label which was false," but also the two instances in the same verdict in which the jury says it finds the defendant "not guilty of misbranding." But we must decline to indulge in such unreasonable straining at the record. It is evident from the record that the jury was not required to and did not intend to render a general verdict on any count of the information here. It was erroneously required to render verdicts in the nature of special verdicts in answer to particulars of the information, and regardless of abstractions about the merits and demerits of that practice in general it is obvious that in this case it was the attempt to apply a sort of special verdict practice that resulted in the void verdicts. None of the numerous criminal cases in which surplusage added to general verdicts of guilty has been deemed harmless can be held to be applicable to the situation here presented. Cf. *Statler v. United States*, 157 U.S. 277; *Patterson v. United States*, 2 Wheaton 221; *Samlin v. United States*, 278 Fed. 170.

Here the jury did not mistakenly add inconsequential matter to a general verdict or anything that can fairly be called surplusage. It complied with the direction given by the court to make special response to special matter stated in paraphrases submitted to them. In consequence its verdict "varied from the issue" and was "bad."

It is further contended for the government that the only fair inference to be drawn from a reading of the whole record of the evidence, the proceedings and the instructions, together with the verdict, is that the jury must have meant that the statements in appellant's letters about the

therapeutic efficacy of his drug, which were its labeling as defined by the Act, were false. We recognize that a verdict even in a criminal case need not be avoided because of slight or inconsequential ambiguity contained in it where that is dispelled entirely and the import is rendered clear and certain by the context of the record of which it forms a part. But the voluminous record here does not present any basis other than mere speculation to conclude that the jury meant to say that the appellant was guilty of anything other than the offense of which they found him guilty. Although the record shows that a great amount of testimony was directed to the issue of false labeling in the letters and we find sufficient evidence to justify a finding if one had been made that there was such false labeling, the fact remains that there was a dispute on that issue of the kind that can only be settled by a jury under our system. That there were differences among the jurors is manifest from the fact that they came into court asking to have their "memories refreshed" as to testimony and as to the instructions and were out altogether twenty seven and a half hours. But if their concurrence finally arrived at was in respect to the labeling found in the letters there was no place in the special forms they were required to fill out to so indicate. They did not so indicate. The conclusion is inescapable that the error in the proceeding was not a mistake in wording or phrasing made by laymen on the jury whose true intent may be verified by reference to other parts of the record. The fatal error was committed in requiring the jury to fill out a special form whose paraphrases included no reference to letters mailed by appellant and which did not permit the jury to make any response to the issue whether false labeling by means of the letters had or had not been committed by the appellant. It can only be concluded that the judgment of conviction is not supported by the verdicts.

It is also argued that the appellant should be deemed to have waived the defects in the forms of verdict because he did not point them out to the court at the time the court delivered them to the jury. But the record shows that the court's attention was called to the defects both before the forms went to the jury and afterwards before the verdicts were arrived at. The court stated,

"The jury can't possibly be misled by the form of verdict in so far as the term



'label' is concerned."

"I can't conceive that there is anything but a rather captious objection to the word 'label' as I used it in the verdict."

As this court's study of the record has led to contrary conclusions and to holding that in consequence of the defects in the forms it has resulted that there was no verdict of guilty of false labeling within the charge of the information, the onus of the outcome may not be shifted to the appellant. He was

put in jeopardy on the charges of the several counts of the information and the jury was discharged without having rendered verdicts of guilty responding to the charges and he is therefore entitled to have the judgment against him avoided.

*[Judgment Reversed and Remanded]*

Reversed and remanded with directions to set aside the judgment and grant a new trial.

**WILLAPOINT OYSTERS, INC., PETITIONER, v. OSCAR  
R. EWING, ADMINISTRATOR, AND J. DONALD  
KINGSLEY, ACTING ADMINISTRATOR,  
FEDERAL SECURITY AGENCY,  
FOOD AND DRUG  
ADMINISTRATION,  
RESPONDENTS<sup>1</sup>**

United States Court of Appeals for the Ninth Circuit. No. 11,936.

April 29, 1949.—— F. 2d——.

A petition for judicial review of two orders of the Federal Security Administrator, prescribing standards of identity and a standard of fill of container for canned oysters, was filed with the court. The court declared that "an advisory announcement" issued under the prior Food and Drugs Act of 1906, with respect to a fill of container for canned oysters, did not confer upon oyster canners a continuing "right" to use the fill specified in the announcement.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

There is no authority which suggests the impropriety or invalidity of a notice of hearing which declared that the standard of fill was "to be fixed on the basis of evidence taken at the hearing."

Sections 401, 701(e), 701(f), Federal Food, Drug, and Cosmetic Act.

The Administrative Procedure Act does not require courts, in review proceedings, to go beyond the limits now generally recognized under the so-called "substantial evidence" rule, or to weigh evidence and substitute their judgment for that of the administrative agency.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

The review provisions of the Administrative Procedure Act and the Federal Food, Drug, and Cosmetic Act are in *pari materia*, and should be considered together and given effect.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

The court declared that the fact that the Administrator's findings with respect to the standard of fill and petitioner's blanching process were in accord with the contentions and evidence of the Government did not demonstrate that the Administrator had considered only Government evidence and disregarded that of the petitioner, and that the findings were sufficiently supported by evidence.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

<sup>1</sup> This opinion properly belongs in the "Review Cases" portion of this book, but was

rendered after that portion had gone to press.  
—Author.



**Federal Food, Drug, and Cosmetic Act***Willapoint Oysters, Inc. v. Ewing et al.*

The common law exclusionary rules of evidence are not based in constitutional interdictions and are not applicable to administrative proceedings, even of judicial character, in the absence of statutory requirement.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

Where voluminous documents are a necessary part of the evidence in a cause, tabulations of these documents may be introduced to aid the trier of the facts. The mass thus testified to should be on hand so that the opposing party may inspect it and use the material for cross-examination.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

Administrative tribunals should be hesitant to exclude an offer of proof; but no prejudice had been created thereby by such exclusion at the administrative hearings.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

A proceeding leading to the promulgation of a definition and standard of identity and standard of fill is a rule-making proceeding, and in legislation, or rule-making, there is no constitutional right to any hearing. No error was committed by a refusal to permit the petitioner to show at the hearing that the chief Government witness and Government counsel had aided and prepared portions of the Administrator's findings and conclusions.

Sections 401, 701(c), 701(f), Federal Food, Drug, and Cosmetic Act.

The petitioner contended that it was unreasonable that a new method of canning oysters, which resulted in a higher quality product, should be destroyed, purportedly to protect the consumer with respect to the fill of container of the product. The court declared that a sufficient answer was that the findings, supported by substantial evidence, were that the higher requirement of fill would not result in impairment of quality when using petitioner's method of canning blanched oysters.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

A court, on review, may not substitute its judgment for that of the Administrator with respect to the wisdom and expediency of a policy determination within the limits of his jurisdiction; the question of "reasonableness" reduces itself to whether the order is a rational conclusion and not so "unreasonable" as to be capricious, arbitrary, or an abuse of discretion. The court declared that in this light, the portion of the order relating to standard of fill was valid.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

The requirement that the Administrator make the actual decision as to the promulgation of regulations under Section 401 does not proscribe the assistance, expertism, and recommendations of his subordinates. It requires more than mere allegation to upset the presumption of validity attaching to public proceedings and the formal recitations of public officials.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

The court declared, with respect to the standard of identity, that, although that was some evidence to support the contention that the Western oyster is known as the "Pacific Oyster," the designation required by the Administrator, the requirement that such oysters be labeled in that manner rather than as "Oysters" was, under the circumstances, arbitrary, capricious, and an abuse of discretion. The requirement as to standard of identity was, therefore, set aside.

Sections 401, 701(f), Federal Food, Drug, and Cosmetic Act.

Albert E. Stephan (Grosscup, Ambler & Stephan, of counsel), Seattle, Washington, for petitioner.



Alexander M. Campbell, Assistant Attorney General, Washington, D.C., Frank J. Hennessy, U.S. Attorney, San Francisco, Calif., (John T. Grigsby, Attorney, Dept. of Justice and William Goodrich, Attorney, Federal Security Administration, Washington, D.C., of counsel), for respondent.

Before STEPHENS, BONE and ORR, Circuit Judges.

**On Petition to Review Orders of the  
Federal Security Administrator**

BONE, Circuit Judge: This matter is before us on a petition for judicial review of two so-called "Final Orders" of the Federal Security Agency, hereafter referred to as Agency, prescribing and establishing standards of identity and a standard of fill of containers for canned oysters. The First Final Order was issued March 10, 1948 by Respondent Ewing, Federal Security Administrator, hereafter referred to as Administrator, and published in Federal Register March 13, 1948 (13 F.R. 1337-1339). The Second Final Order was issued August 3, 1948 by Respondent Kingsley, Acting Federal Security Administrator, and published in Federal Register August 12, 1948 (13 F.R. 4663-4664). These orders which purport to establish regulations of general applicability, will be referred to as the First and Second Orders.

Petitioner, a Pacific Coast packer of canned oysters, filed with this court its petition for judicial review of the First Order and in this petition sought injunctive relief against enforcement of the order of March 10th and an order remanding the proceedings to the Administrator to take further evidence respecting its method of "blanching" oysters which it uses in its commercial canning operations. It was represented to this court that this "blanching" method of treating canned oysters had been "commercially developed" subsequent to the close of the record upon which the Administrator based his First Order of March 10th.

Being persuaded, on the record before us, that the showing made by petitioner presented reasonable and just ground for granting the petition for remand, this court on June 8, 1948, ordered that the proceeding be remanded to the Administrator with directions to take such additional evidence (and evidence in rebuttal thereof) as petitioner should offer relative to the new process it employed to pack "blanched" oysters, the hearing to be held within 30 days of the date of the order, on reasonable notice to petitioner. We further ordered that after considering such additional evi-

ence, the Administrator might modify his findings as to the facts or make new findings by reason of the additional evidence taken, and file with this court such new or modified findings, together with his recommendations, if any, for the modification or setting aside of his original (First) order along with the return of such "additional evidence." (21 U.S.C.A. § 371(f).)

The Administrator conformed to this mandate and pursuant thereto a further hearing was timely held on July 7 to 12, 1948 before a presiding officer designated by respondent Ewing. Thereafter and on August 3, 1948, respondent Kingsley, as Acting Administrator, signed the so-called "Second Order" by which relief was again denied to petitioner. New (supplementary) findings on the new evidence adduced at the hearing ordered by this court were reported back to this court, the supplementary findings being made by Kingsley during the absence from duty of the Administrator. Thereafter petitioner caused the entire record upon which both orders had been made to be presented to this court for consideration, review and determination of the validity of both orders and the findings and conclusions upon which they rest.

Both Final Orders were promulgated under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 341) and they establish and promulgate new "definitions and standards of identity," and new "standards of fill," for canned oysters. As to the matter of "fill," the orders require that *all* oyster packers shall conform to a standard under which the "drained weight" of *all species* of oysters packed in all sizes of cans shall be not less than 59 per cent of the water capacity of the can. As respects standards of identity, the orders require that petitioner's product shall be labeled "Pacific Oysters." (The requirement of a 59 per cent "fill" means that the can (see footnote 3) shall contain approximately 6½ ounces of oyster meat at the time it reaches the consumer. See calculations on weight of oysters and water capacity, *infra*.)

The foregoing requirements are challenged on this review as "unlawful" under each of five enumerated legal standards set by



the Administrative Procedure Act (5 U.S.C.A. § 1009(e)). The specific contentions are set forth at a later point.<sup>1</sup>

The real substance of petitioner's challenge appears to be epitomized in its contention that compliance with the two orders would (a) compel the Western type of oyster to be henceforth *only* identified as "Pacific Oysters" while the Southern type of oyster would enjoy the name "Oysters"; (b) destroy a long-continued use on its labels of the generic term "Oysters" and thereby transfer to Southern oyster canners the exclusive use and good will of that term and (c) destroy petitioner's "quality pack" by requiring an excessive quantity of its (larger) Western oysters to be crammed into a can with resultant discoloration, disfigurement, distortion and breakage.

In order that the numerous contentions of petitioner be brought into proper perspective we are obliged to refer to previous and formal steps taken by the Administrator to establish regulations covering certain practices in the oyster canning industry. Specifically, these activities of the Administrator relate to formal regulatory proceedings before him in 1944. The order and regulations resulting from the 1944 proceedings are discussed more fully *infra*.

The record on this review also contains data and arguments offered by petitioner relating to certain official declarations and actions antedating the 1944 regulatory proceedings before the Administrator, and these are thought by petitioner to support its position here.

A fair consideration of these pre-1944 matters and the argument based on them persuades us (so far as a fill of container standard is concerned) that the subsequent proceedings had before the Administrator in 1944, and the regulations formally and lawfully adopted and promulgated as a result thereof (9 F.R. 14008; 21 C.F.R. 1944 Supp. Sec. 36.6) rob these earlier proceedings of the legal significance petitioner

attaches to them. At the 1944 hearing the issue squarely presented (and made the subject of important regulations) dealt directly and specifically with a formal proposal to establish a fill of container standard for canned oysters. Such a standard *was* duly and lawfully established by the regulations promulgated as a result of this hearing, and it may be noted that a change in such a standard is also one of the basic issues before us on this review.<sup>2</sup> (See later references to the 1944 hearing.)

In reliance upon these so-called "antecedent proceedings" petitioner contends that in using a 5 ounce fill in the No. 1 EO can<sup>3</sup> oyster canners were "following" a so-called "advisory announcement" issued by the Bureau of Chemistry in the Department of Agriculture in February, 1914. This "announcement" recited that "pending further investigation" the weights agreed on by a meeting of canners held in Washington in 1912 would be regarded by the Board as satisfactorily fulfilling the requirements of Food Inspection Decision No. 144.<sup>4</sup>

It appears to be petitioner's position that these early pronouncements (applicable to department policy of the period when they were promulgated) in some manner conferred upon oyster canners a valuable and continuing "right" to use a 5 ounce fill in the No. 1 can, and that this right was destroyed by the order of 1948 here reviewed.

If this is petitioner's position we are unable to agree with it. To follow this reasoning would require us to ignore the compelling legal effect of the subsequent 1944 regulatory order, which we think was lawfully adopted. Whatever the force and effect of these former pronouncements of departmental policy it is certain that the field of regulation they purported to occupy was, under statutory authority, completely pre-empted and occupied by the above mentioned regulations adopted in the 1944 proceedings. The most that can be said of these older "announcements" is that they

<sup>1</sup> Jurisdiction to review the aforesaid orders is conferred by the Food, Drug, and Cosmetic Act (21 U.S.C.A. § 371(f)). The term "Agency" means the Federal Security Agency (21 U.S.C.A. § 321(c)). The term "Administrator" means the Federal Security Administrator (21 U.S.C.A. § 321(d)). See also historical notes to Sections 321 and 392 of Title 21.

<sup>2</sup> The 1944 regulation was silent regarding the character of labels to be placed on cans of oysters. The question of labels for cans, and requirements respecting them, was first dealt with in formal proceedings before the Administrator in 1947, resulting in the First Order

of March 10, 1948 which is here challenged.

<sup>3</sup> This can measures 2-11/16 by 4 inches.

<sup>4</sup> At this time the Bureau of Chemistry had charge of the administration of the Food and Drugs Act of 1906. The Bureau had a Board of Food and Drug Inspection which, in 1912, had issued Decision No. 144. One provision of Decision 144 recited that "canned foods \* \* \* will be deemed adulterated if they are found to contain water, brine, syrup, sauce, or similar substances in excess of the amount necessary for their proper preparation and sterilization." See references in footnote 1.



possess (so far as this hearing is concerned) only historical interest. Subsequent and sweeping statutory changes of vital and compelling significance, and later adoption of new administrative regulations under these statutory changes, completely devitalized these old pronouncements of policy. We cannot view them as having an effect that even remotely touches the issues posed on this review.

The record shows that petitioner was not canning oysters in 1944 (for reasons later stated) as a consequence of which its business operations were not affected by the 1944 regulations which established a standard of fill. Due to this situation it contented itself with entering a formal appearance at the 1944 hearing apparently for the sole purpose of filing (as it did) a challenge to the sufficiency of the evidence there adduced.

The so-called "Southern (oyster canning) Industry" did not appear at the 1944 hearing, and petitioner represents to us that "Western packers could not challenge" the 1944 regulatory order (although they alone had protested) because they were not "adversely affected" within the jurisdictional requirements of 21 U.S.C.A. § 371(f) (1), (Food, Drug and Cosmetic Act).

The 1944 order was published by the Administrator in the Federal Register, November 25, 1944, 9 F.R. 14008-9, the preamble of the order reciting that it was promulgated under his authority as head of the Food and Drug Administration of his Agency. The order further recites that the statutory authority of the Administrator to promulgate the said order derives from 21 U.S.C.A. §§ 341, 343(h) (2) and § 371, the Reorganization Act of 1939 (53 Stat. 561 f.f., 5 U.S.C.A. secs. 133-133v) and Reorganization Plans No. 1 (53 Stat. 1423) and No. 4 (54 Stat. 1234).

There is no doubt in our minds that the 1944 proceedings before the Administrator lawfully established and promulgated regulations applicable to a standard of fill to be observed in the oyster canning industry. Concluding, as we do, that the 1944 regulations were valid, it follows that they continued to be effective and applicable to the business of oyster canning until modified or superseded by subsequent legislation and/or subsequent regulations adopted in compliance with duly ordained standards of administrative procedure.

With this view of the law as a basis we consider certain other facts and circumstances alluded to in petitioner's brief which it asserts also have a material bearing on the issue before us. These matters are also associated with aspects of the history of regulation of the oyster canning industry.

Before 1942 canners of oysters in all areas of the United States filled the No. 1 EO can (the one in principal use) to yield a "drained" or "cut-out" weight of 5 ounces of oysters. By December, 1942 war conditions were such that tin plate was in short supply. In that month a war agency, the War Production Board, issued a "conservation order" (Order M-81) which effectively denied tin plate to oyster canners *except* where the cans (No. 1 EO) were filled to yield at least 7- $\frac{1}{2}$  ounces of oysters. The basis of the WPB conservation order was that the shortage of supply created a "wastage" of tin plate if the 5 ounce fill was continued. This order was a "war measure."

Western (Pacific Coast) oyster canners had been canning oysters since 1928 but upon issuance of the above noted "conservation order" elected to cease canning operations and hence they did not secure tin plate during the so-called "war years." They did not resume canning operations until April, 1946 at which time they again used (in the No. 1 can) the 5 ounce fill of the pre-war period.

At this time (April, 1946) Atlantic and Gulf oyster canners were marketing their oysters with a 7- $\frac{1}{2}$  ounce fill in the No. 1 can. Petitioner refers in its brief to the testimony of a witness for the Food and Drug Administration (at the July 10, 1947 hearing, which resulted in the First Order) that because of this condition "violent complaints" were received by his department from "the Southern industry" then using the 7- $\frac{1}{2}$ ounce fill.

The length of the 1944 order and its ready accessibility to interested persons make unnecessary a recital of its terms. It is sufficient to point out that a department witness testified at the 1947 hearing which resulted in the First Order (March 10, 1948) in the instant case, that the 1944 order of the Administrator established a "fill of container" for canned oysters of a certain (small) size and (it) *was inapplicable to large sized oysters*, that is to Pacific Coast



oysters.<sup>5</sup> This witness stated that the evidence introduced in the 1944 hearing was *insufficient to establish what constituted a proper fill for canned Pacific oysters*; that since that time (1944) such evidence has become available. In his testimony appears reference to "investigations made as early as 1940" which did not result in action on such investigations. It was to reach both questions—"standards of identity" and a "standard of fill" of containers—that the 1947 hearing was held.

#### *The 1947 Hearing*

For the reasons stated above we are persuaded that when the Administrator decided to call the 1947 hearing, his authority to adopt new regulations was not circumscribed by the past events above noted, nor was his program of contemplated action complicated by the necessity of resolving doubts concerning the validity of *any* of these past departmental rulings, regulations or *any* of the past "advisory" opinions purporting to establish rules or regulations of general applicability in the oyster canning industry.<sup>6</sup> By reason of this fact the Administrator faced the 1947 proceedings possessed of full authority to make new regulations or modify existing ones, provided the evidence adduced at the hearing justified, and applicable law supported, the changes he elected to make in this particular field of Federal regulation.

Under date of February 3, 1947 the Administrator issued a formal "Notice to Packers of Canned Oysters," in which he set forth a "Statement of General Policy or Interpretation" in which he announced the intention of the Agency to call a hearing as soon as practicable on proposals to adopt "definitions and standards of identity *and* standards of fill of containers for *all* canned oysters." (Emphasis supplied.) This notice was duly published in the Federal Register of February 7, 1947. It was issued pursuant to Section 3 of the Administrative Procedure Act (5 U.S.C.A. § 1002).

Petitioner is aggrieved because the first advice it received of the above mentioned "Notice" was by its publication in the Fed-

eral Register. It criticizes the notice on the ground that its terms "would appear to indicate that petitioner \* \* \* [was] in some manner violating the [Food and Drug] Act." This criticism is vague and on the face of the record is without merit. (See footnotes 5 and 6.) We find nothing in the record to indicate that petitioner was in any way prejudiced by the form and contents of the Notice, date of issuance and publication.

Following the issuance and publication of the February, 1947 notice, the Administrator took the next formal step in the execution of the program suggested in this notice. On June 6, 1947 he published a "Notice of Hearing" which was to commence July 10, 1947 at Washington, D.C. (The First Order resulted from this hearing.) This formal notice of hearing was published and appears in 12 F.R. 3726.

Petitioner criticizes this "Notice of Hearing" on the ground that it did not advise of any *precise proposal* to change the standard of fill, either by increasing or lowering the then existing standards, i.e., 5 ounces for large oysters and 7½ ounces for small oysters, but left that figure blank "to be fixed on the basis of evidence taken at the hearing." The reference here is to language which discusses proposals to change the terms of the previously (1944) adopted regulations 36.6.

Petitioner cites no authority nor do we find any which suggests the impropriety or invalidity of this sort of notice of hearing or the hearing held pursuant to it. The notice certainly indicated with blunt directness the intention of the Administrator to establish changes in the standard of fill, and in this important respect we find nothing in it which could have misled interested parties to their prejudice. It was phrased in such fashion that they could know exactly what issue they would confront at the hearing. An examination of the recitals in the first part of the notice reveals the purpose of the Administrator to take action on the standard of fill "upon application of a substantial portion of the industry," and

<sup>5</sup> The 1944 order and the proceedings from which it resulted clearly indicate that Pacific type oysters were not brought within the scope of the order or the regulations it prescribed. These regulations (36.6) were limited in their application to oysters weighing *less than* ½ ounce. The 1948 order also clearly indicates that the 1944 order did not include a requirement of fill covering the drained weight of

oysters of "large size," i.e., Pacific oysters.

<sup>6</sup> While the 1944 proceedings before the Administrator superseded all of these and spelled out a wholly new set of rules which were intended to and did completely occupy and dominate the entire field of regulation, the order did *omit* the establishment of "standards of identity."



"upon his own initiative," "and upon proposals of the Administrator," to fix, by regulations, a definition and standard of identity for canned oysters. That sort of definitive language made his purpose abundantly plain.

Being convinced that the procedural steps leading to the 1947 hearing conform in all respects to statutory requirements we proceed to a consideration of that proceeding. If petitioner's charge of invalidity leveled at the First and Second Orders is sound in law, their infirmities must be disclosed by what occurred at that hearing *and* in the subsequent, and additional hearing of 1948 held pursuant to our order of remand.

Preliminary to the inquiry into the 1947 proceedings we think that certain calculations will be helpful in viewing the effects of the regulations assailed in this proceeding. Pertinent references appear in the orders and regulations of 1944 and 1948 concerning the "water capacity" of containers (cans) used by oyster canners. The commonly used can, (the No. 1) has a water capacity of approximately 11 ounces. The relationship of can capacity to the "fill" of oysters is established by the requirements set forth in the noted regulations.

The terms "cut-out weight" and "drained weight" mean the net weight of oyster meat in the can when it reaches the ultimate consumer—in other words, the "fill" of the container.

Assuming for approximate purposes the use of the standard 11 ounce can, the relationship of fill of oysters to can capacity would be as follows: a "drained weight" of 5 ounces of oyster meat would occupy 46% of the water capacity; 6½ ounces of oyster meat would occupy 59%; 7 ounces of oyster meat would occupy 64%, and 7½ ounces of oyster meat would occupy 68%.<sup>7</sup>

The record of administrative proceedings in this case is long and involved. Even a brief summary of its nearly 1200 pages of testimony and the provisions of numerous exhibits (many of involved statistical character) would expand this opinion beyond reasonable limits. However, in meeting the issues posed by a record of this character we have approached the problem with awareness of the duty imposed upon reviewing courts by the Congress. (See 5 U.S.C.A. § 1009(e).) This section of the

applicable Administrative Procedure Act of 1946 (referred to herein as the Act) requires us to "review the whole record or such portions thereof as may be cited by any party" and to set aside agency findings and conclusions "unsupported by substantial evidence." (See also 21 U.S.C.A. § 371 (e).)

We do not view this particular directive (§ 1009(e)) as one requiring us to go beyond the limits now generally recognized under the so-called "substantial evidence" rule, or to weigh evidence and substitute our own judgment for that of the administrative agency. We think that we conform to it when we consider the evidence on both sides in order to determine whether it appears that the evidence in support of the administrative conclusion can fairly be said to be substantial in the face of opposing evidence. We do not indulge the assumption that § 1009(e) (5 U.S.C.A.) invites judges to give a brevet to their fancies, thereby approving adoption of purely subjective judgments in passing upon the validity of administrative regulations, and the orders establishing them.

The rational conclusion respecting the foregoing matter is that judges are not free to evaluate the legal status of challenged regulations on the basis of their individual notions and purely personal views as to the "fairness," sound sense, good business judgments and/or propriety of such regulations when measuring them off against all of the facts and circumstances of administrative proceedings under review. Validation of such a theory would translate review proceedings into a game of chance in which the objecting parties, however untenable their arguments, would have far more than a second bite at the cherry on every conceivable sort of legal and factual issue in the case, and administrative boards would be mere deposition takers for courts of review.

When it enacted the Administrative Procedure Act in 1946, with its review proceedings (5 U.S.C.A. § 1009), Congress did not see fit to amend the provisions of the Food and Drugs Act (21 U.S.C.A. § 371) relating to the scope of review proceedings under the latter Act, and for this reason Circuit courts face the task of harmonizing the review provisions of both pieces of legislation. The review provisions of both Acts are in

<sup>7</sup> The application of this formula is seen in regulatory practice. Consult the provisions of the cited orders of 1944 and 1948, and regula-

tion 36.6 therein. This regulation (of 1944) was replaced by one of the same number by the 1948 order.



*pari materia*; both relate to the same matter or subject, and it is our view that they dovetail and should be considered together and given effect since it cannot be said that they are so inconsistent that to apply them to the record before us would create confusion. We think that this danger does not exist. (See comments pp. 94, 95, Attorney General's *Manual on Administrative Procedure Act*.)

Section 371, *supra*, specifically provides that "the findings of the Administrator as to the facts, if supported by substantial evidence shall be conclusive." (Emphasis supplied). See subdiv. (f) (3).

Related directly to the foregoing provision of Section 371 is the introductory "excepting" cause with which Section 10 of the Act opens (5 U.S.C.A. § 1009) which clause provides that judicial review is available under the Act to any person adversely affected, etc., "except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion." (Emphasis supplied.) (See also 21 U.S.C.A. § 371 (f) (6) holding that the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.)

From the foregoing it would seem clear that "findings of fact" made by the Administrator, if supported by substantial evidence, are conclusive on this review. Cf. *United State ex rel. Trinler v. Carusi*, 166 F. 2d 457, 460, 461.

It is also desirable to make brief reference to the many other applicable provisions of the Act. Particular attention is directed to those provisions defining the meaning of the terms "Rule," "Rule-making," "Order," "Adjudication," "Agency proceeding" and "Agency action." These statutory definitions are applicable in the inquiry at bar.

The Act makes clear that in the proceedings before the Administrator, the proponent of a rule or order must carry the burden of proof. The Act also authorizes the agency to receive *any evidence*, although as a matter of policy it should exclude irrelevant, immaterial or unduly repetitious matters. However, the presence of such matter in the record does not call for reversal of agency action where on the whole record the rule or order issued is supported by reliable, probative and substantial evidence.

The comments of the House member who submitted the Report of its Judiciary Committee on the bill, dealt directly with the

interpretation and intent of the bill which became the Act. In appraising the terms of the bill (which passed unanimously) he stated to the House that the terms "Order" and "Adjudication" used therein cover the *judicial functions* of agencies, and embrace all of the decisions that agencies make *other than* "Rule-making," that is to say, the doing of things which courts otherwise do. The definitions of "Rule" and "Rule-making" apply whenever agencies *are exercising legislative functions and powers*, i.e., when issuing general or particular *regulations* which in form or effect are like the statutes of Congress.

In the noted (and paraphrased) statement of the House member in charge of the bill, he appeared to be adopting accepted analytical terminology.

The above referred to Congressional comment on procedural requirements under the Act serves to illustrate and emphasize important aspects of this legislation.

Under authority conferred by the Act we now dispose of the challenge to the validity of the First and Second Orders. As indicated above, petitioner's brief presents five basic contentions. In these it asserts that the First and Second Orders are unlawful because they were (a) made without observing procedural requirements; (b) unsupported by substantial evidence; (c) in excess of statutory jurisdiction; (d) arbitrary, capricious, and an abuse of discretion and (e) contrary to constitutional rights. Other formal contentions are argumentatively presented in a manner which lays heavy emphasis on six points mentioned below. Of these, three main points are (1) that neither respondent "conscientiously read or considered all of the evidence"; (2) that a witness for the Food and Drug Administration and its counsel either wrote or had a hand in preparing the First Order; and (3) that erroneous rulings upon evidence were made by the hearing examiner.

Subsidiary contentions are that (1) the notice of hearing (of July, 1947) was inadequate; (2) that the conduct of the proceedings was not fair; (3) that the hearing examiner put an unlawful burden of proof upon petitioner at the hearing held after remand by this court.

Fundamentally, these contentions carry us back to two basic questions. First, does the Administrator possess lawful authority to make and promulgate orders containing regulations of the legal character of those under review? Second, if the first question



calls for an affirmative answer (and we think it does) were the proceedings at the hearings which resulted in the promulgation of the First and Second Orders tainted with the infirmities charged by petitioner?

The vigorous and multi-pronged attack on the validity of the procedural steps leading to the promulgation of the First and Second Orders suggests a brief reference to the statutory authority of the Administrator to make the criticised orders, and second, a reference to the authority of this court to set aside either or both of them as "not in accordance with law." As to the first, the pertinent language in 21 U.S.C.A. § 341 (Food and Drugs Act) is a "directive" which sets forth that the Administrator "shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, \* \* \* and/or reasonable standards of fill of container." (Emphasis supplied.)

As to the second matter, the authority to set aside an order on judicial review is found in 21 U.S.C.A. § 371 (f) (3) (6) (Food and Drugs Act), and the scope and legal tests of judicial review are also set forth in the Act, 5 U.S.C.A. § 1009(e). The last cited statute empowers a reviewing court to "hold unlawful and set aside agency action" (i.e., "order"—5 U.S.C.A. § 1001 (g)) which it may find to be "arbitrary, capricious, and abuse of discretion," or as violative of some other provision of said subsection (e).

#### *The Fixing of Standards*

As indicated above, we do not doubt that the Administrator possesses ample statutory authority to adopt Orders, and Regulations of the character of those (36.5 and 36.6) here involved, and we do not understand petitioner to be denying such basic statutory authority. Its petition for review

challenges the validity of the *procedural steps* employed by the Administrator which eventuated in the adoption of the regulations embodying the "requirements" it objects to—it does not object to the exercise of the basic statutory authority underlying *valid* official pronouncements of their character.

At the outset of this opinion we pointed out that petitioner's challenge was directed against the "requirements" for a 59% "fill" of oysters, and the type of identifying label to be used on its canned product, that is, "Pacific Oysters." If these "requirements" in the regulations are "reasonable" (under 21 U.S.C.A. § 341) it is beyond the power of this court to set them aside unless it can be said upon the entire record, that the agency proceedings underlying and establishing the orders (agency action) promulgating the challenged regulations were so irregular and conducted with such indifference to, or in such defiance of, statutory procedural requirements, as to rob them of any lawful basis or authority for their existence. If the record shows such to be the case (as petitioner charges) then the orders are invalid. (See 5 U.S.C.A. § 1009(e).)

#### *Standard of Fill*

The justification for the Administrator's order is his belief that any oyster canning method which ultimately results in a container but one-half full of oysters is unfair to the consumer, and that a mere statement on the label of the ounce content of drained oysters<sup>8</sup> is not sufficiently curative. In short he feels that the consumer is entitled to receive more oyster meat and less liquid.

Petitioner answers that by its method, "blanching," (described below),<sup>9</sup> the highly nutritious liquid content of the oyster is saved and the oyster is thus suspended in

<sup>8</sup> Suggested by the court on oral argument as a possible alternative. Petitioner thereafter did so label his product.

<sup>9</sup> The raw oysters are taken from the shell and dipped in a hot brine solution for a period of 30 to 60 seconds. They are then washed in fresh water, cooled, and held in warm water until ready to be canned. In order to obtain a net drained weight of 5 ounces of oyster meat, each 11 ounce can is then filled to 7½ ounces of oysters and the balance is filled with water to which a salt tablet is added. The conveyor carries the can to the sealing machine where a "topper plunger" pushes the oysters down into the can and the sealing machine then seals it. The can is then subjected to heat for sterilization and preservative purposes for 30 minutes which causes the oyster to lose liquid content into the packing medium.

This loss is approximately 2½ ounces per can—the oysters have already lost approximately 16% of their weight in the blanching process. The packing medium is then enriched by this "nectar" and soluble solids. Tests made for petitioner by independent laboratories tend to show that this nectar contains nutritional value and is of some use as a separate drink or as a flavoring for oyster stews.

Large oysters of any species, because of their size, are better able to retain this "nectar" (roughly corresponding to the lymph, blood, and liquid content of the tissues of mammals) in the initial application of heat when the smaller oyster loses it. Thus the latter has little or none of this liquid to exude into the packing medium during the sterilization process in the can and shrinks very little if any.



a perfect packing medium, all of which results in a much higher quality product. Further, because of the shrinkage of the oyster after the can is sealed, it is impossible to utilize the blanching method and retain a finished product containing more than five ounces of oyster meat *unless* in the canning process the oysters are "crammed" into the can resulting in a much higher incidence of "twisting, tearing, breaking and browning." Petitioner further complains that this will result in an excessive waste of oysters in the sealing process<sup>10</sup> by "clipping" of the top oysters which then protrude from the top of the can.<sup>11</sup> This will result in a higher number of imperfect oysters. The total result, petitioner asserts, can only be the destruction of the high good will and consumer acceptance it has built up over a period of years.<sup>12</sup> It claims that it now enjoys 60% of the market for Western oysters.

The Administrator found, and there was evidence tending to show, that the eleven ounce can *could* be filled to yield 6½ ounces net drained weight<sup>13</sup> by the use of the blanching method without a substantial increase in the incidence of the above mentioned detractive features. Both the Government and petitioner conducted various tests of oysters packed to conform to the 6½ ounce drained weight standard, with a variance in results not uncommon in tests of such a character. Petitioner's scientists arbitrarily assigned a certain number of demerits to the above-mentioned factors of twisting, browning, etc., in accordance with the believed consecutive effect of each upon consumer acceptance. This method is not to be denounced, indeed, it was probably the only computative method possible, excluding an actual consumer reaction test, but the weight apportioned to each factor and the alleged results of the tests were all questions of fact which the Administrator had to resolve. The organoleptic examinations of the Government, on the other hand, were probably less efficiently conducted and

with less scrupulous regard to strict scientific media,<sup>14</sup> but we do not find they contain the infirmities so vigorously asserted by petitioner. Moreover the conclusions drawn therefrom are strongly supported by the results of a commercial buyer's preference examination by the Government covering seven Seattle wholesale buyers who had extensive experience in buying and selling canned oysters,<sup>15</sup> in that the buyers reached substantially the same conclusions as the Government chemists who conducted the organoleptic examinations. Moreover highly qualified and experienced agency personnel witnessed the actual canning of various of the test packs canned to equal the new higher drained weight standard. On the basis of their own observations they testified that little trouble was encountered and that the new standard could be met even without alteration of machinery or method.

Merely because the findings were in accord with the contentions and evidence of the Government does not demonstrate to us that the Administrator considered only Government evidence and disregarded that of the petitioner. Even though *we* might feel that petitioner's evidence was the more convincing, and *we* might have concluded differently, the evidence considered in its entirety, is clearly sufficient to support the findings made. At the risk of tautology, it might not be amiss to reemphasize that this court does not try facts<sup>16</sup> where factual conclusions are drawn from substantial evidence supporting opposed contentions. We will only delve sufficiently deep to ascertain whether the evidence adduced will logically and rationally permit the findings made. Section 10(e) of the Administrative Procedure Act provides that

"In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and due account shall be taken of the rule of prejudicial error."

This was not intended to require reviewing courts to weigh the evidence and make independent findings of fact; rather, it means

<sup>10</sup> See footnote 9.

<sup>11</sup> There is a certain amount of "clipping" when the can is filled to equal the 5 ounce result; thus petitioner contends that logically there must be a higher percentage of clipping when more oysters are placed in the can. There is also some evidence that the oysters tend to rise somewhat in the warm water packing medium.

<sup>12</sup> Petitioner first inaugurated its blanching method subsequent to the taking of evidence preceding the first final order of March 10, 1948. See opinion, p. 2 *supra* [second paragraph

of this opinion]. Prior to that time it had used a pre-steaming method.

<sup>13</sup> By filling the can to approximately 9 ounces.

<sup>14</sup> See Crocker, McGraw-Hill *Series in Food Technology, Flavor*, (1945).

<sup>15</sup> The administrator could certainly believe it significant that petitioner never attempted to impeach the alleged results of this test by cross-examination.

<sup>16</sup> See *Grace Bros. v. Commissioner*, No. 11,976, decided by this court February 18, 1949 and authorities cited therein.



that in determining whether agency action is supported by substantial evidence, the reviewing court should consider all the evidence in its measure as an integrated whole and not just the evidence favoring only one side.<sup>17</sup> We hold the findings to be sufficiently supported.

It now remains for us to examine the proceedings in the light of their alleged statutory and constitutional defects.

#### *Admissibility of Hearsay*

Petitioner vigorously complains of the admission of certain hearsay evidence primarily consisting of documentary reports of certain inspectors of the Food and Drug Administration not present for cross examination.

The common law exclusionary rules of evidence are not based in Constitutional interdictions and are not applicable to administrative proceedings, even of judicial character, in the absence of statutory requirements.<sup>18</sup> Neither § 701(f)(3) of the Food, Drug and Cosmetic Act, *supra*, nor § 7(c) of the Administrative Procedure Act, *supra*, so requires, either expressly or by implication from the language used. To the contrary, the later Act enjoins that:

" \* \* \* Any oral or documentary evidence may be received, but every agency shall as a matter of policy provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except upon consideration of the whole

record or such portions thereof as may be cited by any party and as supported by and in accordance with the reliable probative, and substantial evidence." (Emphasis supplied.)<sup>19</sup>

Thus the receipt of such evidence, over objection, and even if "immaterial, irrelevant," etc., is not such a grievous error as to require reversal.<sup>20</sup> The receipt of irrelevant, immaterial and hearsay evidence is no cause for reversal of an administrative order though the validity of the order can never rest upon conjecture, guess or chance.

However, both the Food and Drug Act and the Administrative Procedure Act enjoin in effect that the findings are to be in accord with the substantial evidence and in that posture are conclusive upon the reviewing tribunal.<sup>21</sup> This is but a restatement of the general rule of judicial review applied by appellate tribunals to the findings of facts of lower courts.<sup>22</sup> The requirement that the administrative findings accord with the substantial evidence does not forbid administrative utilization of probative hearsay in making such findings. Such construction would nullify the first portion of section 7(c) (Administrative Procedure Act) providing for the receipt of such evidence.

The degrees of probative force and reliability of hearsay evidence are infinite in variation, and its use by administrative bodies *ex necessitate*, must in part be governed by the relative unavailability of other and

<sup>17</sup> Senate Hearings, p. 1359 (1941); Attorney General's Manual, *supra*, p. 110. Administrative Procedure Act—Legislative History, 79th Cong., 2nd Session, 1944-46, Sen. Doc. No. 248, p. 279: "'Substantial evidence' means evidence which on the whole record is clearly substantial, plainly sufficient to support a finding or conclusion under the requirements of section 7(c), and material to the issues. It is exceedingly important. Difficulty has come about by the practice of agencies and courts to rely upon something less—suspicion, surmise, implications, or plainly incredible evidence. Although the agency must do so in the first instance, under this bill it will be the duty of the courts to determine in the final analysis and in the exercise of their independent judgment whether on the whole of the proofs brought to their attention the evidence in a given instance is sufficiently substantial to support a finding, conclusion, or other agency action or inaction. In reviewing a case under this fifth category the court must base its judgment upon its own review of the entire record or so much thereof as may be cited by any party." (Emphasis supplied.)

<sup>18</sup> *Opp Cotton Mills v. Adm'r.*, 312 U.S. 126, 155 (1940).

<sup>19</sup> "Such evidence [irrelevant, immaterial, etc.] is useless and to be excluded as a matter of efficiency and good practice." Sen Doc. 248

*supra*, pp. 364-365. Note that there is no lay jury to be protected from improper influence.

<sup>20</sup> See *Edison Co. v. Labor Board*, 305 U.S. 197, 229-230 (1938); *Tagg Bros. & Moorhead v. United States*, 280 U.S. 420, 422 (1930); *United States v. Abilene & So. R. Co.*, 265 U.S. 274, 288 (1924); but cf. *Int. Comm. Com. v. Louisville & Nashville R. Co.*, 227 U.S. 88, 93 (1913); *Powhatan Mining Co. v. Ickes*, 118 F. 2d 105 (6-Cir. 1941). See also Attorney General's Manual, *supra*, pp. 77-78; Stephan, Fact-Finding Boards and Rules of Evidence, 24 A.B.A.J. 630, 636 (1938).

<sup>21</sup> 21 U.S.C.A. 371(f)(3) (Food and Drug Act) provides: "\* \* \* The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive." The same result is reached by the Administrative Procedure Act, 5 U.S.C.A. § 1009, where the reviewing court is directed to "set aside agency action, findings, and conclusions found to be \* \* \* (5) unsupported by substantial evidence \* \* \* subject to the requirements of sections 1006 and 1007 \* \* \*". Sections 1006 and 1007 involve hearings and procedure in cases of rule making (§ 1003) and adjudication (§ 1004).

<sup>22</sup> That this is the purpose of the Administrative Procedure Act see Attorney General's Manual, *supra*, p. 93 and reference to section 10(e), p. 230 Senate Doc. 248, *supra*.



better evidence. However, since "substantial evidence" includes more than "uncorroborated hearsay" and "more than a mere scintilla,"<sup>23</sup> the findings, to be valid, cannot be based upon hearsay alone, nor upon hearsay corroborated by a mere scintilla. Founded upon these requirements, the test whether evidence is "substantial," is whether, in the individual case before the court, there is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."<sup>24</sup>

An exhaustive search of the entire record convinces us that the portion of the order relating to fill satisfies this test and there was no abusive and thus reversible use of hearsay.<sup>25</sup>

Further, even though some of the findings may be questionable, such findings merely lose their conclusive character, i.e., lose any persuasiveness they may have had upon the reviewing court.<sup>26</sup> But, when as here, there are sufficient validly supported findings to uphold an administrative order, the court may not upset it.

#### *Exclusion of Bases of Tabulation*

Petitioner also complains that although Government Exhibit 33, a tabulation in summary of the findings and results of certain Government tests, was admitted into evidence, the worksheets upon which it was based were excluded; further, that comparison discloses that the tabulation is not a true representation of such worksheets, and thus not of the true result of the tests.

As we held in *Augustine v. Bowles*,<sup>27</sup> the rule is that

"Where voluminous documents are a necessary part of the evidence in a cause, it is well settled that tabulations of these documents in the form of charts and schedules may be introduced for the aid of the trier of fact. 4 Wigmore (3d Ed.) § 1230. Most courts require that the mass thus summarily testified to, if

the occasion seems to require it, be placed on hand in court so that the opposing party may inspect it and use the material for cross-examination."

To this rule we adhere. Petitioner had adequate access to these worksheets and utilized the information gained therefrom for its cross-examination. Thus, to this point, there is no error.

The trial examiner refused to permit the worksheets to become part of the record by virtue of petitioner's offer of proof so that the validity of the contention that Exhibit 33 did not truly memorialize the worksheets could be examined on review. The reason assigned for the denial was that since the worksheets would become part of the official records, the Administrator would have adequate access to them. However, the worksheets as such, not being in the record, are not before us.<sup>28</sup>

Petitioner's use of the excluded worksheets in its cross-examination served in effect, as its offer of proof. It "extracted" those items which it (both here and below) alleges as discrepancies. Thus we may examine in the record, the matter so extracted.<sup>29</sup> If all of the worksheets were in the record we would not feel constrained to examine other than the portions thereof to which our attention was directed. Such is the normal rule and is embodied in section 10(e) of the Administrative Procedure Act, *supra*, which provides in part:

" \* \* \* the court shall review the whole record or such portions thereof as may be cited by any party, \* \* \*"

Further, petitioner may not urge here alleged errors and discrepancies between the worksheets and Exhibit 33 which it did not bring to the attention of the trial examiner and may not allege here for the first time that it had an inadequate opportunity for a sufficient comparison.

To exclude an offer of proof is a danger-

<sup>23</sup> *Edison Co. v. Labor Board*, 305 U.S. 197, 229-230 (1938).

<sup>24</sup> *Ibid.* p. 229; See discussions in *Penn. R. Co. v. Chamberlain*, 288 U.S. 333, 339-343 (1933); *Ballston-Stillwater Co.*, 98 F. 2d 758, 760 (2-Cir. 1938); *N.L.R.B. v. Thompson Products*, 97 F. 2d 13, 15 (6-Cir. 1938); *Appalachian Electric Power Co. v. N.L.R.B.*, 93 F. 2d 985, 989 (4-Cir. 1938); see also Daniels, *Jud. Review of Fact Findings of the Federal Trade Commission*, 14 Wash. L. Rev. 37 (1939).

<sup>25</sup> *Washington Coach Co. v. N.L.R.B.*, 301 U.S. 142, 147 (1937); *Del Vecchio v. Bowers*, 296 U.S. 280, 287 (1935); *Florida v. United States*, 292 U.S. 1, 12 (1934); *Fed. Trade Comm. v. Algoma Lumber Co.*, 291 U.S. 67, 73 (1934).

<sup>26</sup> *Cf. N.L.R.B. v. Norfolk Corp.*, 109 F. 2d 128, 130 (4-Cir. 1940); *N.L.R.B. v. Empire Furn.*

*Corp.*, 107 F. 2d 92, 94 (6-Cir. 1939); *Appalachian Electric Power Co. v. N.L.R.B.*, *supra*, footnote 24.

<sup>27</sup> 149 F. 2d 93, 96 (9-Cir. 1945) and authorities cited. See also *Harper v. United States*, 143 F. 2d 795, 804-806 (8-Cir. 1944); and, 4 Wigmore § 1231 (3d ed.). *Cf. Wilkes v. United States*, 80 F. 2d 285, 291 (9-Cir. 1937); *Shreve v. United States*, 103 F. 2d 796 (9-Cir. 1939).

<sup>28</sup> We would have the worksheets certified up to us if we believed it were necessary to a proper disposal of this case.

<sup>29</sup> Petitioner nowhere contends that his opportunity to examine and compare the worksheets was inadequate and he did not request additional time for this purpose of the trial examiner.



ous and imperfect practice.<sup>30</sup> Administrative tribunals should be hesitant and reluctant to indulge in such practices. However, each case must be determined on its individual facts and we find no prejudice here. We have examined the alleged discrepancies and errors both in the record and as stated by petitioner's brief and find them to be minor and unsubstantial. They clearly do not show, as petitioner contends, that Exhibit 33 is "honeycombed with error."

#### *Rule-Making or Adjudication*

Petitioner attempted to show at the second hearing, and here alleges, that the chief Government witness Callaway and Government counsel aided and prepared portions of the findings and conclusions, contrary to section 5(c) of the Administrative Procedure Act, *supra*, which in part provides:

"No officer, employee, or agent engaged in the performance of investigative or prosecuting functions for any agency in any case shall, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review \* \* \*."

The proof was denied on the ground that this proceeding fell into the category of "rule-making" and the prohibitory section above, applied only to "adjudication" and was thus not involved.

The Administrative Procedure Act is based upon a broad and logical dichotomy between "rule-making" and "adjudication," i.e., legislative and judicial functions. In the framework of the Act, separate sections deal with *rule-making* and *adjudication*; section 4 is concerned with the former, section 5, the latter. Sections 7 and 8 fix

rules governing hearings and decisions applicable to both classes of proceedings. Section 5(c) does not and was not intended to apply to instances of rule-making.<sup>31</sup> Petitioner however, contends that even in cases of rule-making, when sharply contested issues of fact are involved adjudication procedures should be followed. Cited in support thereof are excerpts from Congressional hearings<sup>32</sup> to the effect that in such a situation, "good practice" would be for the agencies to follow the rules laid down for adjudications. As a matter of policy, such may be true, but the Act as finally enacted did not so provide and we cannot believe that the omission was the result of oversight.

We turn now to whether the proceeding here involved was *rule-making* or *adjudication*. If adjudication, then the action of the trial examiner in denying proof of participation by prosecuting officials in the findings, etc., was error and the case must be remanded.

Rule-making is legislation on the administrative level, i.e., legislation within the confines (standard) of the granting statute as required by the Constitution and its doctrines of non-delegability and separability of powers.<sup>33</sup> Section 2(c) of the Administrative Procedure Act, *supra*, defines rule-making as the "agency process for the formulation, amendment, or repeal" of agency statements of:

"general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy \* \* \*."

This is not novel reasoning but an explanation of existing concept and must be so

<sup>30</sup> Another questionable practice is that of hearing officers who hold much of the discussion and argument concerning the relevancy of evidence, etc., "off the record."

<sup>31</sup> In rule-making, "\* \* \* the parties will be better served if the proposed decision—later required by section 8—reflects the views of the responsible officers in the agencies whether or not they have actually taken the evidence." Sen. Doc. 248, *supra*, p. 361; Attorney General's Manual, *supra*, pp. 50-58, 128.

The second and third sentences of section 5(c) provide for the separation of functions of hearing and decision from functions of investigation and prosecution. The second sentence provides:

"Save to the extent required for the disposition of ex parte matters as authorized by law, no such officer shall consult any person or party on any fact in issue unless upon notice and opportunity for all parties to participate; nor shall such officer be responsible to or subject to the supervision or direction of any officer, employee, or agent engaged in the performance of investigative or prosecuting

functions for any agency."

It applies generally to the hearing process or the making of the record. Its broad purpose is to assure that hearings be conducted by hearing officers who have not received or obtained factual information outside the record and who are neither supervised nor directed in their conduct by investigative or prosecuting officials of the agency. In substance, no evidentiary or factual information may be received until, after notice, all parties are permitted to participate.

The third sentence, part of which is quoted in the body of this opinion, applies generally to the decisional process or the making of the recommended or initial decision. Its purpose is to insure decisions free from the participation or advice of officials engaged in investigative or prosecuting functions. This we conceive, would include aid, advice, or actual preparation of portions of the findings and conclusions.

<sup>32</sup> Sen. Doc. 248, *supra*, pp. 185, 203-4, 216.

<sup>33</sup> See *Panama Refining Co. v. Ryan*, 293 U.S. 388, 421 (1935).



construed. The legislative process, i.e., rule-making, is normally directed primarily at "situations," rather than particular persons.<sup>34</sup> Individual protestations of injury are normally and necessarily lost in the quantum of the greater good.

Adjudication, defined by section 2(d) of the Administrative Procedure Act as any action other than rule-making but including licensing comports with the judicial function. Its primary concern is with individual rights, liabilities for past conduct, or present status under existing law,<sup>35</sup> and tends to be accusative and disciplinary in nature.

Each definition necessarily is couched in terms of "tendency," its object, the so-called "clear case." The concepts are not wholly mutually exclusive but each to a degree contains elements of the other. In explication, it is an essence of legislation, functionally speaking, that in its immediate effect, it hurts some and benefits other members of society.<sup>36</sup> In the twilight region, (often termed "quasi"), intermediating the poles of clarity, the doctrine of primary purpose controls.<sup>37</sup> So tested, we are without serious doubt that this was a rule-making proceeding. This is true even though the result of the order is of immediate and grave economic import to petitioner.

Petitioner also complains that permitting the prosecutor to prepare portions of the findings and conclusions violates its constitutional right to a fair hearing. However in legislation, or rule-making, there is no constitutional right to any hearing whatsoever.<sup>38</sup> Thus the requirements of any hearing are to be tested solely by the statute so providing, which may or may not import constitutional concepts. As shown *supra*, this was not done by the pertinent sections of the Administrative Procedure Act so far as concerns separation of functions in rule-making proceedings. Thus petitioner's rights, neither statutory nor constitutional, have been violated.

It must be noted that even in adjudications, there is no constitutional prohibition against the findings and conclusions being drawn by the successful party at the direction or with the permission of either a trial judge or administrative hearing officer. To so declare would cast unjustifiable opprobrium upon the trial bench of both the Federal and State judiciary. In judicial proceedings, the separation of judge and litigant necessary for a minimum of fairness is in that portion of the decisional process involved in *actually making the decision*.<sup>39</sup> It cannot be contended that mere

<sup>34</sup> Yet note the cases on legislative divorces, etc. *Sparhawk v. Sparhawk*, 116 Mass. 315 (1874); *Bingham v. Miller*, 17 Ohio 445 (1848); *Wilkinson v. Leland*, 27 U.S. 627 (Pet. 1829); *Maynard v. Hill*, 125 U.S. 190 (1888); see also Benton, *The Distinction Between Legislative and Judicial Functions*, 8 A.B.A. Rep. 261, 264-265 (1885); Pound, *Justice According to Law*, 14 Col. L. Rev. 1, 11-12 (1914); Sharp, *The Classical American Doctrine of "The Separation of Powers"*, 2 U. of Chi. L. Rev. 385 (1935).

<sup>35</sup> Probably the best definition discovered by the writer is: "Legislation is the creation by the state of a right (including an authority, a privilege or an immunity), duty or status not dependent on the existence of a previous right, duty or status."

"Adjudication is the imposition of a specific duty in personam, or of a liability, or the granting of a right or status which is dependent on a previous right or duty, in that it is imposed by way of giving effect to a right or duty determined to exist or have existed, or by way of redress or punishment for its violation." Green, 29 Yale L. Rev. 369, 372-373 (1920); See also, Fuchs, *Procedure in Administrative Rule-Making*, 52 Harv. L. Rev. 259, 263 (1938); Hyneman, *Administrative Adjudication: An Analysis*, 51 Pol. Sci. Q. 383, 516 (1936).

<sup>36</sup> Compare the language of Mr. Justice Stone in *Miller v. Schoene*, 276 U.S. 272, 279 (1928); and Luce, *Legislative Problems*, (1935) p. 60: "In the last analysis nearly every law transfers something from A to B. It matters not

whether this advantage be tangible or fancied, large or small. Somebody gains, somebody loses, for you cannot create an advantage out of a vacuum. This makes the whole question one of degree and there is no principle, no fundamental right, in a matter of degree."

<sup>37</sup> See *Morgan v. United States*, 298 U.S. 468, 479 (1936); *Louisville & Nashville R. Co. v. Garrett*, 231 U.S. 298, 307 (1913); *Prentiss v. Atlantic Coast Line*, 211 U.S. 210, 226-227 (1908).

<sup>38</sup> *Bowles, etc. v. Willingham et al.*, 321 U.S. 503, 519 (1944); In *Bi-Metallic Investment Co. v. State Board*, 239 U.S. 441 (1915), Holmes, speaking for the court said, at p. 445: "Where a rule of conduct applies to more than a few people it is impracticable that every one should have a direct voice in its adoption. The Constitution does not require all public acts to be done in town meeting or an assembly of the whole. General statutes within the state power are passed that affect the person or property of individuals, sometimes to the point of ruin, without giving them a chance to be heard. Their rights are protected in the only way that they can be in a complex society, by their power, immediate or remote, over those who make the rule."

<sup>39</sup> *Lee v. Fleming*, 158 F. 2d 984, 987 (Emer. C.C.A. 1946); *N.L.R.B. v. Baldwin, etc.*, 128 F. 2d 39 (3-Cir. 1942) and authorities cited p. 52 *et seq.*; *Berkshire Employees Ass'n. v. N.L.R.B.*, 121 F. 2d 235, 238-9 (3-Cir. 1941); *Maitland v. Zanga*, 14 Wash. 92, 44 Pac. 117 (1896); *Jones on Evidence*, § 764 (2d ed. 1908).



drawing of the findings is participation in the actual decision. The requirement of section 5(c) of separation of functions in adjudications arose as the result of extensive public criticism of the fairness of hearings in which the trier of fact and the investigative and prosecuting officials were members of the same agency and often exchanged duties.<sup>40</sup>

*Reasonableness: Limits of the Granting Statute*

Petitioner also contends that under the particular facts of this case the standard of "reasonableness" by which the delegation of legislative authority to the Administrator is limited, has been exceeded.<sup>41</sup> In other words, it is argued that it is unreasonable that a new method of canning oysters which results in a much higher quality product as shown by established and increasing consumer acceptance should be destroyed, purportedly to protect that very consumer. Therein lies much superficial persuasiveness. A short and sufficient answer is that the findings supported by substantial evidence are, in substance, that the higher requirement of fill will not result in impairment of quality when using petitioner's method of canning blanched oysters.

The problem facing the Administrator is the wisdom and expediency of a policy determination within the limits of his jurisdiction. As to these matters a court on review may not substitute its judgment.<sup>42</sup> Within the Administrative Procedure Act, administrative discretion encompasses any of the number of policy decisions which can be supported by a given set of "substantial" factual data. Within that range his conclusions may not be judicially tampered with, excepting of course for procedural violations. The question of "reasonableness" reduces itself to whether the order is a rational conclusion and not so "unreasonable" as to be capricious, arbitrary or an abuse of discretion. In this light too, we hold the portion of the order relating to standard of fill to be valid.

*Allegation that Administrator Did Not Consider the Evidence*

The First Order was signed by respondent, Ewing, Federal Security Administrator. It recited that it was made "on the basis of the evidence received at the above entitled hearing duly held pursuant to notice." The Second Order, signed by respondent Kingsley, then Acting Administrator, recited that the supplemental findings and conclusions were made "on the basis of evidence" received at the second hearing. This recitation in and of itself does not state that respondent Kingsley included in his consideration the evidence taken at the first hearing but various of the supplemental findings refer to the transcript of the evidence and exhibits of the first hearing. From this, petitioner is impelled to accuse both officials of not conscientiously reading and considering all of the evidence. This despite letters from respondent Ewing to petitioner's attorneys that he "personally" and "thoroughly" considered evidence (necessarily of the first hearing) and found it to be substantially in support of the order.

Section 341 of Title 21, Food and Drug Act, *supra*, provides:

"Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, \* \* \*." (Emphasis supplied.)

This provision of applicable law requires the Administrator (or Acting Administrator) to himself make the actual decision. Section 8 of the Administrative Procedure Act providing for initial decisions, findings and conclusions by subordinates, does not affect the above noted requirement, and section 12 of the latter act specifically states

in judges."

<sup>40</sup> *Inland Steel Co. v. N.L.R.B.*, 109 F. 2d 9 (7-Cir. 1940); *Montgomery Ward & Co. v. N.L.R.B.*, 103 F. 2d 147 (8-Cir. 1939); *Brinkley v. Hassig*, 83 F. 2d 351 (10-Cir. 1936); *Palmer v. Ultimo*, 69 F. 2d 1 (7-Cir. 1934), cert. den. 293 U.S. 970 (1934). But see Jaffe, *Investive and Investigation in Administrative Law*, 52 Harv. L. Rev. 1201, 1218-1219 (1939): "It may well be that a sincere conviction as to public policy predisposes the mind where it might otherwise be in a position of doubt or balance on a conflict of fact or a choice of applicable principle. But to announce out of hand that such a state of mind constitutes a 'disqualification' is in part quixotic and in part non-sequitur. A strong and sincere conviction as to certain laws may exist and does often exist

in judges."

<sup>41</sup> 21 U.S.C.A. § 341 (Food and Drug Act). Exceeding this limit is specifically made cause for reversal by section 10(e)(B)(3) of the Administrative Procedure Act.

<sup>42</sup> *Fed. Sec. Adm'r. v. Quaker Oats Co.*, 318 U.S. 218 (1943); *Power Commission v. Pipeline Co.*, 215 U.S. 575, 586 (1942); *Gray v. Powell*, 314 U.S. 402, 412 (1941); *N.L.R.B. v. Link Belt Co.*, 311 U.S. 584, 596-597 (1941); *Rochester Tel. Corp. v. United States*, 307 U.S. 125, 145-146 (1939); *Shields v. Utah Idaho R. Co.*, 305 U.S. 177, 185 (1938); *United States v. Carolene Products Co.*, 304 U.S. 144, 151 (1938); and *Swayne & Hoyt v. United States*, 300 U.S. 297, 304 (1937).



that "Nothing in this Act shall be held to \* \* \* limit or repeal additional requirements imposed by statute \* \* \*."<sup>43</sup> The requirement that the Administrator make the actual decision does not proscribe the assistance, expertise, and recommendations of his subordinates. His would otherwise be an impossible task. Within this area of permissible reliance, the options of procedure granted agencies and the limits imposed upon them by the Administrative Procedure Act control. Thus hearing officers in cases of adjudication, and other subordinates as well in cases of rule-making, may make and draw findings of fact, conclusions of law and recommended or initial decisions. The Administrator need examine the record only so far as to exercise an independent judgment, but this does not preclude reliance upon findings, supported by substantial evidence, and prepared by competent subordinates.<sup>44</sup> He may reject, modify or accept the findings and conclusions, in whole or in part, but acceptance does not indicate a failure to perform the duty imposed upon him by law. Congress did not intend to make of him another trial examiner, requiring of him new findings of fact *de novo* on the record. His burden is making the ultimate decision on policy based upon the facts so found.

Both the first and second hearings culminating in the respective First and Second Orders were conducted by the same trial examiner. We entertain no doubt respondent Kingsley had the benefit of any differences in the evidence at the two hearings. His references in the supplemental findings to portions of the evidence taken at the first hearing disclose to us, in the absence of *proof* to the contrary, that he sufficiently examined all necessary evidence. Further, the evidence to be taken on our order of remand was solely upon the narrow issue whether the alleged new method (blanching) of preparing oysters for canning justi-

fied any modification of the First Order. However, as we have said, we are sufficiently convinced that all proper evidence, both of the first and second hearings received adequate consideration at the hands of the Administrator and the Acting Administrator.

Furthermore, we cannot allow the Administrator's recitation that he has personally examined and considered the evidence in making his decision to be successfully challenged by a mere allegation in a brief. We have neither moral nor legal right to presume that only those who occupy judicial office respect their obligations and perform their official duties honestly, sincerely and conscientiously. Nor can we presume the subordinate personnel to be a camarilla. It requires more than mere allegation (or affidavit on information and belief, which is not even found here) to upset the presumption of validity attaching to public proceedings and the formal recitations of public officials.<sup>45</sup>

#### *Standard of Identity*

Petitioner also urges that to permit packers of Eastern and Southern oysters (*ostrea virginica*) the option of either labeling their product "Cove Oysters," or "Oysters," while requiring Western canners of the so-called "*ostrea gigas*" to label their product "Pacific Oysters," is to "unreasonably" give exclusive use of the generic term "oysters" to the Eastern and Southern packers when that term applies equally to both. With this we are inclined to agree.

The Food and Drug Act, 21 U.S.C.A. § 341, permits the Administrator to promulgate a *reasonable* definition and standard of identity "for any food, under its common or usual name so far as practicable."<sup>46</sup> There is some evidence in the record to support the contention that the Western oyster (*ostrea gigas*) is known as the "Pacific oyster" even though this geographic term would seem to include the smaller native "Olympia" oyster (*ostrea lurida*) and

<sup>43</sup> See Attorney General's *Manual on the Administrative Procedure Act*, p. 139 *re* section 12.

<sup>44</sup> In the first *Morgan* case, 298 U.S. 468, 481-482 (1936), the Court stated: "\* \* \* the officer who makes the determinations must consider and appraise the evidence \* \* \*" but, "This necessary rule does not preclude practicable administrative procedure in obtaining the aid of assistants in the department. Assistants may prosecute inquiries. Evidence may be taken by an examiner. Evidence thus taken may be sifted and analyzed by competent subordinates."

<sup>45</sup> *N.L.R.B. v. Ford Motor Co.*, 118 F. 2d 766

(9-Cir. 1941); *N.L.R.B. v. Biles Coleman Co.*, 98 F. 2d 16 (9-Cir. 1938); *N.L.R.B. v. Lamp Cotton Mills Co.*, 108 F. 2d 568, 569 (5-Cir. 1940); *N.L.R.B. v. Botany Worsted Mills*, 106 F. 2d 263 (3-Cir. 1939); *Cupples v. N.L.R.B.*, 103 F. 2d 953, 957 (8-Cir. 1938); *Cf. Twin City Milk Producer's Ass'n. v. McNutt*, 122 F. 2d 564, 123 F. 2d 396 (8-Cir. 1941); *Columbia Cheese Co. v. McNutt*, 137 F. 2d 576, 580 (2-Cir. 1943).

<sup>46</sup> *Fed. Sec. Adm'r. v. Quaker Oats Co.*, *supra*, Note 42; *Twin City Milk Producer's Ass'n. v. McNutt*, *supra*, Footnote 45; *Columbia Cheese Co. v. McNutt*, *supra*, Footnote 45.



even though the so-called Pacific oysters canned by petitioner have for years been known locally as "Japanese oysters".<sup>47</sup> Such evidence showing that *ostrea gigas* are known as "Pacific" oysters we may accept. However, if the order is "not in accordance with law," (i.e., "unreasonable," see Section 341 *supra*) 21 U.S.C.A. § 371 (f) (3), or is "arbitrary, capricious, an abuse of discretion or not otherwise according to law," Administrative Procedure Act, § 10 (e) *supra*, it must be set aside.

The Second Order, insofar as it related to standard of identity, was but a restatement of the First Order, and thus there is in effect but one order relating to standard of identity. It purports to regulate the entire oyster industry, thus on review it must be examined in the light of, and viewed against, the background of the entire industry. Even though a portion of an order, lifted from context, may be supported, we think that it may be extremely arbitrary, capricious and unreasonable when examined in the light and against the background of the order's entire effect. Such is the situation we find here.

Permitting one segment of a sea food industry to enjoy the exclusive use of a term naturally associated with and normally applied to an article of food in common use under a common name, without the most cogent reasons directly pertinent to the protection of the consuming public, appeals to us as being outside the bounds of reason and fairness. A purchaser who inspects the two products side by side, one labeled "Oysters," the other "Pacific Oysters,"

would probably be left with the impression that the latter are in some form atypical, possibly not a true member of the oyster family. We think that the danger inherent in such a situation makes it manifestly unfair to that portion of the industry discriminated against, and to that extent we regard the requirement as arbitrary, capricious and an abuse of discretion. The requirement as to "Standard of Identity" is therefore set aside.

The foregoing disposition of the issues in this case is without prejudice to the promulgation of any further order relating to standard of identity which avoids the arbitrary discrimination above noted.

To be sure there is some evidence in the record that consumers distinguish the Eastern and Southern from the "Pacific" oysters by virtue of the large size<sup>48</sup> of the latter. However there is neither a scintilla nor iota of evidence in the entire record that anyone considers the Eastern and Southern product only to be "oysters." Any conclusion resting upon such an assumption cannot be said to be founded upon substantial evidence, or upon any evidence at all, within the requirements of the Administrative Procedure Act, § 10 (e) *supra*.

Our consideration and disposition of this case has been greatly aided by excellent briefs and by the able presentation of the issues by counsel for both parties.

The orders under review are ordered enforced in part in accordance with this opinion.

(Endorsed:) Opinion. Filed Apr. 29, 1949.  
Paul P. O'Brien, Clerk.

<sup>47</sup> Cf. *Introduction of Japanese Oysters into the United States*, Bureau of Fisheries Circular No. 12, August, 1932.

<sup>48</sup> We cannot remain insensible to the fact

that various of the Eastern and Southern oysters, notably the Lynnhaven and Chincoteague varieties, grow to sizes which may equal that of the "Pacific" oyster.



THE UNITED STATES OF AMERICA, PETITIONER, v.  
 FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF  
 DEVICE, MORE OR LESS LABELED  
 "SINUOTHERMIC," ETC.<sup>1</sup>

United States Supreme Court. No. 640. October Term, 1948. May 2, 1949.  
 336 U.S. 804

Certiorari denied (1949).

Reversing 172 F. 2d 386. See page 521. See also pages 212, 249.

In a prior opinion, the Supreme Court had held that the separate shipment of machines and leaflets describing their uses constituted a single interrelated activity. On remand, the Court of Appeals concluded that because there were several shipments of machines and a single shipment of advertising matter, it was not clear which shipments might be considered a single interrelated activity and remanded the case to the District Court for a determination of that fact. Since the function of the leaflets and the purpose of their shipment had been established, nothing more was needed to show that the movements of the machines and leaflets constituted a single interrelated activity.

Sections 201(m), 304(a), 502(a), Federal Food, Drug, and Cosmetic Act.

The Supreme Court declared that the United States was entitled to a hearing before the Court of Appeals on the question whether the evidence as respects the falsity of the diagnostic capabilities of the machines was adequate to sustain their condemnation, even though error in exclusion of evidence as to the therapeutic or curative value of the machines were conceded.

Sections 304(a), 502(a), Federal Food, Drug, and Cosmetic Act.

PER CURIAM.

The question presented by this petition is whether the Court of Appeals followed our mandate on remand of the cause in 335 U.S. 355.

The case when it was here earlier this Term appeared in the following posture:

A condemnation proceeding was instituted by the United States under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U.S.C. § 334). Sixteen machines with alleged diagnostic and curative capabilities had been shipped in interstate commerce. Leaflets describing the uses of the machine had been shipped at a separate time. The Court of Appeals had held that the separate shipments of the machines and leaflets precluded a conclusion that the leaflets had accompanied the device in interstate commerce, and therefore the transaction was outside the reach of the Act. We reversed the Court of Appeals and held that the separate shipment of the machines and leaflets constituted a single interrelated activity.

On remand the Court of Appeals concluded that because there were several shipments of machines and a single shipment of advertising matter, it was not clear which shipments might be considered a single interrelated activity. Therefore, it remanded the case to the District Court for a determination of this fact.

When the case was here before we decided that the facts of separate shipments of machines and leaflets was immaterial. The controlling factors were whether the leaflets were designed for use with the machine and whether they were so used. Since the function of the leaflets and the purpose of their shipment were established, nothing more was needed to show that the movements of the machines and leaflets constituted a single interrelated activity. Moreover, the case is not complicated by shipments of machines and leaflets to different persons. One Kelsch was the recipient of both.

On remand the Court of Appeals adhered to its former ruling that the District Court erroneously excluded evidence as to the therapeutic or curative value of the machines. When the case was here before we did not disturb that ruling. But we did leave to the Court of Appeals for consideration a further question—whether the evidence as respects the falsity of the diagnostic capabilities of the machine was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question.

The petition for certiorari is granted and the judgment is

*Reversed.*

<sup>1</sup> This opinion properly belongs in the "Seizure Cases" portion of this book, but was

rendered after that portion had gone to press.—Author.



## TRADE CORRESPONDENCE

This part sets forth informal opinions rendered by the Food and Drug Administration on many problems which have arisen under the Act. These opinions are excerpts from day-by-day replies to inquiries concerning the application of the statute to specific problems. They represent the attitude of the Administration in the light of the facts submitted and other available information. Thus, the views expressed are subject to modification by the Administration as additional facts may become available and controlling decisions are rendered by the Federal courts.

In November 1945, a new "TC" (trade correspondence) series, similar to the old, was commenced. Items in the new series were numbered 1-A, 2-A, etc., to distinguish them from trade correspondence contained in the earlier series. Only eight opinions were issued under the "A" series, however.

After passage of the Administrative Procedure Act in 1946, 60 Stat. 237, the Food and Drug Administration concluded that opinions which would otherwise have emanated as trade correspondence should thereafter be issued more formally. New opinions of the Administration were therefore published in the Federal Register as "Statements of General Policy or Interpretation." This change, together with the passage of time since the enactment of the Federal Food, Drug, and Cosmetic Act, has resulted in the issuance of fewer opinions in the recent past.

### TO DISTRIBUTORS OF SULFANILAMIDE AND RELATED DRUGS

Sulfanilamide and drug preparations containing sulfanilamide or related compounds for indiscriminate use by the general public, in a manner which constitutes a serious danger to health, are, when found in interstate commerce, actionable under Section 502(j) of the Act.

TC-1—August 26, 1938

It is the consensus of qualified experts that sulfanilamide is a valuable aid in the treatment of several serious disease conditions when the dosage is properly adjusted to the requirement of the individual patient and frequency of dosage and duration of treatment are intelligently and expertly directed. It is further the consensus of such experts that, when used under other conditions, it is a dangerous drug, capable of causing serious injury and even death.

In the light of these facts, careful consideration has been given to the status of

sulfanilamide under the provisions of the Food, Drug, and Cosmetic Act which deal with traffic in dangerous drugs.

Sulfanilamide and drug preparations containing sulfanilamide or related compounds for indiscriminate use by the general public, in a manner which constitutes a serious danger to health, are, when found in interstate commerce, actionable, in the opinion of the Food and Drug Administration, under Section 502(j) of the Federal Food, Drug, and Cosmetic Act, which section of the law is now in effect.

### TO DISTRIBUTORS OF AMINOPYRINE AND RELATED DRUGS

Aminopyrine and drug preparations containing it, when found in interstate commerce under labeling which may result in their use by the general public, are actionable under Section 502(j) of the Act. There is causal relationship between the drug and agranulocytosis.

TC-2—September 8, 1938

Although aminopyrine has been employed as a drug for more than 40 years and although agranulocytosis has been recognized

as a clinical entity for the past 16 years, the role of aminopyrine as probably the most important causative factor in agranulocytosis was not recognized until about 6 years ago.



Once the causal relationship between the drug and the disease was suspected confirmatory evidence rapidly accumulated and was reported in medical literature. There is now no doubt that this drug has been responsible for numerous deaths in the United States.

In the light of these facts, careful consideration has been given to the status of aminopyrine under the currently effective

provisions of the Food, Drug, and Cosmetic Act which deal with traffic in dangerous drugs.

In the opinion of the Food and Drug Administration, aminopyrine and drug preparations containing it, when found in interstate commerce under labeling which may result in their use by the general public, are actionable under Section 502(j) of the Federal Food, Drug, and Cosmetic Act.

#### TO DISTRIBUTORS OF CINCHOPHEN, NEOCINCHOPHEN, AND RELATED DRUGS

Cinchophen, neocinchophen, and drug preparations containing them, when found in interstate commerce under labeling which may result in their use by the general public, are actionable under Section 502(j) of the Act.

TC-3—September 8, 1938

Since the introduction of cinchophen as a therapeutic agent some 30 years ago, many reports of its toxic manifestations have been reported in medical literature. These include numerous cases of acute yellow atrophy and cirrhosis of the liver which result in permanent damage and not infrequently in death. The dangerous potentialities of this drug are now generally recognized by informed physicians.

The toxic properties of neocinchophen are generally similar to those of cinchophen.

In the light of these facts, careful con-

sideration has been given to the status of cinchophen and neocinchophen under the currently effective provisions of the Food, Drug, and Cosmetic Act which deal with traffic in dangerous drugs.

In the opinion of the Food and Drug Administration, cinchophen, neocinchophen, and drug preparations containing them, when found in interstate commerce under labeling which may result in their use by the general public, are actionable under Section 502(j) of the Federal Food, Drug, and Cosmetic Act.

#### AMINOPYRINE, CINCHOPHEN, NEOCINCHOPHEN, SULFANILAMIDE

and related products, and all drugs which may be dangerous to health unless used under appropriate supervision, will be regarded as misbranded if they are not labeled with a warning so conspicuous as certainly to arrest attention, and in such informative terms as will not fail to apprise the user of the danger of irreparable injury if the article is consumed without adequate and continuous medical supervision.

TC-4—(Undated)

You are familiar with the trade notices issued by this Administration on August 26 and September 8, 1938, relating to the distribution of preparations containing aminopyrine, cinchophen, neocinchophen, sulfanilamide, and related products. In brief, these notices announced the Administration's opinion that such drugs, if distributed so that they would be used by the general public without appropriate medical supervision, would be regarded as misbranded in violation of Section 502(j) of the Food, Drug, and Cosmetic Act.

Following the issuance of those announcements, manufacturers generally placed upon their labels such warnings as "To be used under the direction of a physician only,"

with or without a statement to the effect that the drug has been reported to have caused untoward reactions in some individuals.

That these warnings are not adequate to prevent the indiscriminate distribution and use of such drugs is obvious from the fact that, notwithstanding such labelings, they are reaching the general public in considerable quantities.

The purpose of this letter is to inform you that to effect the obvious purpose of the law in the protection of the public health, preparations of the character referred to above will be regarded as misbranded if they are not labeled with a warning so conspicuous as to certainly arrest attention, and in such informative



terms as will not fail to apprise the user of the danger of irreparable injury if the article is consumed without adequate and continuous medical supervision.

It should be understood that this principle applies not only to the specific drugs which

were dealt with in the trade announcements referred to above, but is applicable to all drugs which may be dangerous to health unless used under appropriate supervision.

Please acknowledge receipt of this letter.

### NOTICE TO MANUFACTURERS OF HAIR DYE PREPARATIONS

All coal-tar hair dyes must bear labeling prescribing adequate preliminary tests. Directions furnished by the trade correspondence are acceptable and are given as a guide. Other tests may also be acceptable.

Section 602(c) of the Act requires that the caution statement provided by Section 601(a) for coal-tar hair dyes appear on the label in a prominent and conspicuous place.

TC-5—October 17, 1938

Sections 601(a) and 902(a) of the Food, Drug, and Cosmetic Act require, among other things, that after September 23, 1938, a coal-tar hair dye which may be injurious to users shall bear the statement

"Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

It is necessary, as provided in the caution statement, that all such hair dyes bear labeling prescribing adequate preliminary tests. For the benefit and guidance of those interested, there are published herewith directions which, in the light of present knowledge and information, are regarded as acceptable. This information is given merely as a guide and does not mean that other tests may not be acceptable.

#### DIRECTIONS FOR MAKING SKIN TEST

(1) The hair dye contained in this package must never be used for dyeing the hair unless a preliminary skin test has been made. The skin test must be made each and every time before the hair is to be dyed, regardless of whether or not a skin test has been made at some time previously.

(2) The dye used for the preliminary skin test must be a portion of the article intended to be used for dyeing the hair.

(3) The sample of dye to be used for the preliminary skin test should be mixed and prepared in exactly the same manner and

according to the directions applicable to the actual use of the hair dye itself.

(4) By means of a suitable applicator (clean camel hair brush, cotton-tipped applicator, or other applicator) a streak of dye not less than a quarter of an inch wide and at least one-half inch long is made on the skin and scalp behind one ear. It is IMPORTANT that the streak of dye extend into the hairy portion of the scalp as well as that portion of the skin that is hairless.

(5) The streak of dye should be permitted to remain for at least 24 hours. The test should be read between 24 and 48 hours after application. Preferably the test area should *not* be covered with any type of dressing, and contact with combs, hats, spectacles or any other object should be avoided.

(6) Warning: If redness or burning, or itching, or small blisters, or any other type of eruption appears in the general area used for the skin test during the first 24 hours, the individual is sensitive to the dye, and under no circumstances should it be used for dyeing the hair. Hair dyes should not be used when there is any disease or eruption present anywhere on the skin or on the scalp.

Section 602(c) requires that the caution statement appear on the label in a prominent and conspicuous place. This requirement would be met if the caution statement appears conspicuously in a color that contrasts with the background and the remainder of the printed matter. The caution statement should appear on the main panel of the label with the name of the product.



**NOTICE TO EYEBROW AND EYELASH DYE MANUFACTURERS**

Severe injury and blindness have resulted from application to eyelashes and eyebrows of dyes containing paraphenylenediamine, and such products violate the Act.

Injurious effects are caused by paratoluylenediamine, and eyelash and eyebrow dyes containing it in any amount will be considered adulterated under Section 601(a).

The use of oils, argyrol, magnesium carbonate, paper shields, etc., cannot guarantee protection of the eyes against dangerous products such as paraphenylenediamine and paratoluylenediamine.

TC-6—November 8, 1938

The toxic effect of paraphenylenediamine is well known. A number of persons have suffered severe injury, and in some cases blindness has resulted from the application of this dye to the eyelashes and eyebrows. There is no doubt that preparations containing this dye are in violation of the Food, Drug, and Cosmetic Act and accordingly legal action under the law has been instituted against them.

Inquiries have been received as to the propriety of substituting paratoluylenediamine for paraphenylenediamine in these preparations. The Food and Drug Administration has obtained very definite evidence of injury from this dye. Based upon a serious consideration of the injurious effects of paratoluylenediamine, eyelash and eyebrow dyes containing paratoluylenediamine

in any amount will be considered adulterated under Section 601(a) of the Act and appropriate action taken.

It has also been noted that substances such as oils, argyrol, magnesium carbonate, paper shields, etc., are customarily included in packages of eyelash and eyebrow dye preparations to be used to prevent the introduction of the dye into the eyes. It is the opinion of the Administration that the use of these precautionary measures cannot guarantee protection of the eyes against such dangerous products as paraphenylenediamine and paratoluylenediamine.

This notice should not be interpreted as indicating that other dyes used for eyelash and eyebrow dyeing are to be accepted as meeting the requirements of Section 601(a) of the Food, Drug, and Cosmetic Act.

**NOTICE TO PACKERS, SHIPPERS AND IMPORTERS OF CHEESE**

Individual cheeses of the brick, Limburger or Roquefort type are properly classified as food in package form and the provisions of the Act, such as Sections 403(e) and (f), are applicable thereto. Under authority of Section 902(a)(2), the Secretary of Agriculture has designated cheeses as exempt from the requirements of Section 403(i)(2), relating to listing of ingredients on label, for a reasonable period of two years pending the formulation of definitions and standards of identity.

TC-7—February 28, 1939

Service and Regulatory Announcements, Item 292, issued October 9, 1918, under the Food and Drugs Act of 1906, exempted from net weight declaration individual cheeses of the brick and Limburger types and individual, imported Roquefort cheese wrapped in tin foil and parchment paper. At the time this opinion was rendered it was the contention of the cheese industry that these particular cheeses were not in package form because of their invariable sale by the pound and not by the unit and that the paper and foil used were an integral part of the cheese.

From observations of current practices and from the reports of State food, weights,

and measures officials, it is evident that cheeses of the particular types mentioned in Item 292 are now commonly sold in uniform size units. Furthermore, from reports of State officials, such individual cheeses are not regarded as exempt from the operations of State laws and, accordingly, confusion has arisen in the mind of packers on account of the apparent difference between the Federal Act and State laws.

It is evident to this Administration that individual cheeses of the brick, Limburger or Roquefort type as described in Item 292 are properly classified as food in package form under the provisions of the Food, Drug, and Cosmetic Act of 1938. Opinion 292 will therefore be automatically rescind-



ed on June 25, 1939, the effective date of the new Act. The provisions of the new Act applicable to food in package form will be applied to such articles. To insure compliance with Section 403(e) and (f) of the Act the net weight statement and the name and place of business of the manufacturer, packer, or distributor should be conspicuously set forth on the principal display panel or panels of the label. The common

or usual name of the article should also be conspicuously stated. Under authority of Section 902(a)(2) the Secretary has designated cheeses as exempt from the requirements of Section 403(i)(2) relating to listing of the ingredients on the label for a reasonable period of two years pending the formulation of definitions and standards of identity.

---

### NOTICE TO PRODUCERS AND SHIPPERS OF CORN MEAL

Corn meal made from corn containing rotten grains, insect-infested grains, etc., is adulterated. Interstate shipments are subject to seizure and the shippers are liable to the Act's penal provisions.

Suggestions are made in the trade correspondence for the purpose of contributing to the elimination of the use of unfit corn in the production of corn meal for food.

TC-8—May 9, 1939

Investigations by the Food and Drug Administration of plants producing corn meal for human consumption have shown the grinding at some mills of corn containing rotten grains, insect-infested grains, insect larvae and excreta, pieces of corn cobs, and rodent excreta. Corn meal made from such corn showed similar evidence of filth and extraneous matter.

Corn meal for human food made from such raw materials and showing such filth is adulterated within the meaning of the Federal Food and Drugs Act of 1906, and the Food, Drug, and Cosmetic Act which supersedes it. Interstate shipments of such meal are subject to seizure and the shippers liable to the penal provisions of these acts.

Producers and shippers of corn meal should take immediate steps to insure the consumer a product at all times free from decomposition and such objectionable foreign material. The following suggestions are made for constructive purposes and are intended to contribute to the elimination of

the use of unfit corn in the production of corn meal for food:

(1) Only clean, sound corn, free from spoiled, rotten, insect-infested, or moldy grains and free from rodent excreta, should be used in the manufacture of corn meal for human food.

(2) Prompt and careful inspection of deliveries of corn should be made to permit of immediate rejection of unfit lots. Special attention should be given to corn bought unshucked.

(3) Attention should be given to milling machinery and storage facilities at corn meal plants with a view to positively insuring against contamination from insects and rodents.

(4) The education of all producers and handlers of corn from whom supplies of corn are obtained should be undertaken so as to reduce damage and infestation by insects and rodents to the end that only sound, clean corn will be delivered to mills for manufacture of corn meal.

---

### NOTICE TO MANUFACTURERS OF MERCURY BLEACH CREAM

Mercury preparations represented as bleaching agents are cosmetics and drugs. Bleach preparations which contain more than 0.2 per cent bichloride of mercury or comparable amounts of other mercury compounds will be the subject of regulatory action. Products which contain 5 per cent or less of ammoniated mercury may not violate the statute if they bear conspicuous warnings. Adequate directions for conducting tests should appear in labeling as well as advice against use by children under 12.

TC-9—May 13, 1939

Many inquiries have been received by the Food and Drug Administration requesting an expression of opinion concerning the

status of mercury preparations represented as bleaching agents or to remove, prevent, or cure tan or freckles. These articles are cosmetics within the meaning of the statute



because they are intended to promote the attractiveness and to alter the appearance of the person. They are also drugs because they are intended to affect the structure and function of the body.

After a study of the problem, during the course of which the opinion of many qualified experts was ascertained, the conclusion has been reached that the broad claims made for some such articles are misleading. To the extent to which they remove the skin structures involved, the products are harmful.

Bleach preparations which contain large amounts of ammoniated mercury are being proceeded against under Sections 502(j) and 601(a) of the Food, Drug, and Cosmetic Act. Such preparations containing more than 0.2 per cent bichloride of mercury or comparable amounts of other mercury compounds will be the subject of immediate regulatory attention.

Based on such information as is now available, it is our opinion that products which contain 5 per cent or less of ammoniated mercury may not violate the statute if they bear conspicuous warnings designed to acquaint purchasers with the

fact that if skin irritation appears after application, use of the product should be immediately discontinued; that such articles should not be applied to irritated or damaged skins, such as cut, bruised, sunburned, or sore skin, after shaving, or after using a depilatory; that prolonged use may produce unsightly discoloration; and that application to a large area of the body is dangerous.

It is an established fact that an unusually large percentage of persons can not tolerate mercury bleach compounds containing ammoniated mercury. Adequate directions for conducting a preliminary test, and for repetition of such testing, should, therefore, appear in the labeling. The warning should further advise against use of the article by children under twelve years of age. The directions for use should provide against vigorous application and should direct that a thin layer is to be applied and left on for not more than one-half hour and then cleaned off with some such substance as benzine or oil.

Claims made for such articles should be limited to such temporary lightening effect as they possess.

### NOTICE TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF COSMETICS

Trade correspondence lists typical examples of claims that are regarded as false or misleading for cosmetics under Section 602(a), such as "Rejuvenating Cream," "Hair Restorer," "Scalp Food," "Skin Firm," "Tissue Cream," etc. The designation of a product by the name of one ingredient, to the exclusion of all others, may also result in misbranding.

TC-10—August 2, 1939

A survey made by the Federal Food and Drug Administration in planning a regulatory program in the enforcement of Subsection 602(a) of the Federal Food, Drug, and Cosmetic Act indicates the probability that a substantial proportion of the cosmetic industry has not realized that certain names and statements which have long been employed in the labeling of cosmetics may contravene requirements of the statute which have now become effective.

The extent to which the use of such claims which may be regarded as false and misleading prevails suggests the propriety of a general notice to the trade to encourage appropriate label revision. It is, of course, not practicable to list all the claims that may be unwarranted; the following, however, are typical examples of some that are regarded as false or misleading:

Contour cream  
Crow's-foot cream  
Deep pore cleanser  
Depilatories for permanent removal of hair  
Products represented as depilatories but which merely bleach the hair  
Eyelash grower  
Eye wrinkle cream  
Hair color restorer  
Hair grower  
Nail grower  
Non-allergic products  
Peroxide cream  
Rejuvenating cream  
Scalp food  
Hair Restorer  
Circulating cream



Enlarged pore preparations  
 Hair revitalizing preparations  
 Muscle oil  
 Nourishing cream  
 Pore paste  
 Skin conditioner  
 Skin firm  
 Skin food  
 Skin texture preparations  
 Skin tonic  
 Stimulating cream  
 Tissue cream  
 Wrinkle eradicator  
 Cosmetics represented as valuable because of their vitamin content

A number of preparations have also been encountered which appear to be misbranded because they are represented as containing ingredients not actually present or present in insignificant proportions.

The designation of a product by the name of one ingredient, to the exclusion of all others, may also result in misbranding. Paragraph (b) under Section 602(A) of the general regulations for the enforcement of the Food, Drug, and Cosmetic Act provides in part that "the labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients."

### STATUS OF CORN SUGAR UNDER FOOD, DRUG, AND COSMETIC ACT

Former ruling on refined corn sugar (dextrose) that it need not be declared on the label of a product in which sugar is a recognized element cannot be re-issued entirely under the new law. For the new law provides for label disclosure of all ingredients in unstandardized foods and requires the holding of public hearings for the purpose of securing substantial evidence upon which definitions and standards of identity may be based.

It is the purpose of the Department, in the formulation of definitions and standards of identity for food, to recognize, where the evidence of record justifies, the optional use of sugar and dextrose without label declaration of either.

TC-11—August 2, 1939

The U. S. Department of Agriculture has announced that in formulating definitions and standards for foods it will recognize—where the evidence of record justifies—the optional use of sugar and dextrose (refined corn sugar) without label declaration of their presence.

This, in effect, perpetuates the ruling on corn sugar issued by former Secretary of Agriculture Hyde under the Federal Food and Drugs Act on December 26, 1930. That ruling became void when the Federal Food, Drug, and Cosmetic Act, on June 25, 1939, replaced the Act of 1906. It cannot be re-issued entirely under the new law, which provides for label disclosure of all ingredients in unstandardized foods and requires the holding of public hearings—in advance of the formulation of a definition and standard of identity for any food—for the purpose of securing substantial evidence upon which the final definition and standard may be based. The recognition given dextrose in each individual standard, and the question of label declaration of sugar and dextrose used as optional ingredients, therefore de-

pend exclusively upon the character and sufficiency of the evidence introduced at the public hearing required by law preliminary to the promulgation of standards.

The text of the Department's statement, made by Secretary Wallace on July 25, follows:

On December 26, 1930, Secretary Arthur M. Hyde issued the following ruling on the status of corn sugar under the Federal Food and Drugs Act of June 30, 1906:

"Corn sugar (dextrose) when sold in packages, must be labeled as such; when sold in bulk must be declared as such; but the use of pure refined corn sugar as an ingredient in the packing, preparation or processing of any article of food in which sugar is a recognized element need not be declared upon the label of any such product.

"Nothing in this ruling shall be construed to permit the adulteration or imitation of any natural product such as honey by the addition of any sugar or other ingredient whatever."

The effect of this ruling, issued under the



Food and Drugs Act of June 30, 1906, expired with the repeal of that law on June 25, 1939.

The ruling cannot be reissued in its entirety under the new Federal Food, Drug, and Cosmetic Act. One reason for this is a new provision requiring label disclosure of all ingredients, including sugar and dextrose (refined corn sugar), in foods for which no definitions and standards of identity have been prescribed. Another reason is that, in prescribing a definition and standard of identity for any food under the new law, the Secretary of Agriculture must base his find-

ings exclusively upon substantial evidence of record introduced at a public hearing on such definition and standard. The recognition given dextrose in each individual standard, therefore, and the question of label declaration of sugar and dextrose used as optional ingredients, depend wholly upon the character and sufficiency of the evidence.

It is the purpose of the Department in the formulation of definitions and standards for food to recognize, where the evidence of record justifies, the optional use of sugar and dextrose (refined corn sugar) without label declaration of either.

### FLAVORING EXTRACTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Provisions of Act most generally applicable to flavoring extracts and flavors will be found in Sections 402, and 403(a), (c), (d), (e), (f), (i), and (k). Sections 201(k) to (n), inclusive, and 303(c) and the corresponding regulations, if any, should be especially noted.

Flavors should contain no ingredients that may render them injurious to health.

Flavor labels should not be false or misleading in any particular.

The terms "extract" and "flavor" are not synonymous. The term "extract" implies an alcoholic product.

Composition of vanilla and other extracts, and composition of vanilla and other flavors, discussed.

Discussion of method of labeling imitation flavors, discussion of artificial colors, chemical preservatives, and artificial flavoring.

TC-12—Reprinted June, 1941

#### *Applicable Provisions of the Act*

The provisions of the Act that are most generally applicable to flavoring extracts and flavors will be found in Sections 402 and 403(a), (c), (d), (e), (f), (i), and (k). Among other provisions of the Act, Sections 201(k) to (n) inclusive and 303(c) and the corresponding regulations, if any, should be especially noted.

#### *Two General Requirements*

Flavors should contain no ingredients that may render them injurious to health.

Flavor labels should not be false or misleading in any particular. The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

#### *Distinction Between "Extract" and "Flavor"*

The vehicle or menstruum of a flavoring extract is ethyl alcohol of proper strength. The terms "extract" and "flavor" are not synonymous. The term "extract" implies an alcoholic product. Flavoring products prepared with vehicles other than alcohol

should be labeled with the term "flavor." Articles labeled "lemon flavor," "orange flavor," etc., should contain the same kinds and proportions of flavoring ingredients as are contained in lemon (or orange etc.) extract. The term "flavor" as used in this article will include both extracts and non-alcoholic flavors.

#### *Composition of Vanilla and Other Extracts*

One U. S. gallon of vanilla extract should contain the soluble matter from not less than 13.35 ounces (avoirdupois) of vanilla beans. Some manufacturers use only 12.8 ounces of vanilla beans per gallon, in the mistaken belief that this quantity is proper. The finished flavor should contain at least 35 per cent of alcohol by volume to keep this soluble matter in solution.

Pending the establishment of standards for specific flavoring oils and extracts, the following articles should have the composition indicated in each case.

**ALMOND EXTRACT.** The flavoring extract prepared from oil of bitter almonds, free from hydrocyanic acid. It contains not less than 1 per cent by volume of oil of bitter almonds.



**OIL OF BITTER ALMONDS, COMMERCIAL.** The volatile oil obtained from the seed of the bitter almond (*Amygdalus communis* L.), the apricot (*Prunus armeniaca* L.), or the peach (*Amygdalus persica* L.).

**ANISE EXTRACT.** The flavoring extract prepared from oil of anise. It contains not less than 3 per cent by volume of oil of anise.

**OIL OF ANISE.** The volatile oil obtained from aniseed.

**CELERY SEED EXTRACT.** The flavoring extract prepared from celery seed or the oil of celery seed, or both. It contains not less than 0.3 per cent by volume of oil of celery seed.

**OIL OF CELERY SEED.** The volatile oil obtained from celery seed.

**CINNAMON EXTRACT, CASSIA EXTRACT, CASSIA CINNAMON EXTRACT.** The flavoring product prepared from oil of cinnamon. It contains not less than 2 per cent by volume of oil of cinnamon.

**OIL OF CINNAMON, OIL OF CASSIA, OIL OF CASSIA CINNAMON.** The lead-free volatile oil obtained from the leaves or bark of *Cinnamomum cassia* (L.) Blume. It contains not less than 80 per cent by volume of cinnamic aldehyde.

**CEYLON CINNAMON EXTRACT.** The flavoring extract prepared from oil of Ceylon cinnamon. It contains not less than 2 per cent by volume of oil of Ceylon cinnamon.

**OIL OF CEYLON CINNAMON.** The lead-free volatile oil obtained from the bark of the Ceylon cinnamon (*Cinnamomum zeylanicum* Nees). It contains not less than 65 per cent by weight of cinnamic aldehyde and not more than 10 per cent by weight of eugenol.

**CLOVE EXTRACT.** The flavoring extract prepared from oil of cloves. It contains not less than 2 per cent by volume of oil of cloves.

**OIL OF CLOVES.** The lead-free volatile oil obtained from cloves.

**GINGER EXTRACT.** The flavoring extract prepared from ginger. It contains in each 100 cubic centimeters the alcohol-soluble matters from not less than 20 grams of ginger.

**LEMON EXTRACT.** The flavoring extract prepared from oil of lemon, or from lemon peel, or both. It contains not less than 5 per cent by volume of oil of lemon.

**OIL OF LEMON.** The volatile oil expressed, without the aid of heat, from the fresh peel of the lemon (*Citrus limonia* Osbeck), with or without previous separation of the pulp and peel.

**TERPENELESS EXTRACT OF LEMON.** The flavoring extract prepared by shaking oil of lemon with dilute alcohol, or by dissolving terpeneless oil of lemon in dilute alcohol. It contains not less than 0.2 per cent by weight of citral derived from oil of lemon.

**TERPENELESS OIL OF LEMON.** Oil of lemon from which all or nearly all of the terpenes have been removed.

**NUTMEG EXTRACT.** The flavoring extract prepared from oil of nutmeg. It contains not less than 2 per cent by volume of oil of nutmeg.

**OIL OF NUTMEG.** The volatile oil obtained from nutmegs.

**ORANGE EXTRACT.** The flavoring extract prepared from oil of orange, or from orange peel, or both. It contains not less than 5 per cent by volume of oil of orange.

**OIL OF ORANGE.** The volatile oil obtained, by expression or alcoholic solution, from the fresh peel of the orange (*Citrus aurantium* L.). It has an optical rotation (25°C.) of not less than +95° in a 100-millimeter tube.

**TERPENELESS EXTRACT OF ORANGE.** The flavoring extract prepared by shaking oil of orange with dilute alcohol, or by dissolving terpeneless oil of orange in dilute alcohol. It corresponds in flavoring strength to orange extract.

**TERPENELESS OIL OF ORANGE.** Oil of orange from which all or nearly all of the terpenes have been removed.

**PEPPERMINT EXTRACT.** The flavoring extract prepared from oil of peppermint, or from peppermint, or both. It contains not less than 3 per cent by volume of oil of peppermint.

**PEPPERMINT.** The leaves and flowering tops of *Mentha piperita* L.

**OIL OF PEPPERMINT.** The volatile oil obtained from peppermint. It contains not less than 50 per cent by weight of menthol.

**ROSE EXTRACT.** The flavoring extract prepared from attar of roses, with or without red rose petals. It contains not less than 0.4 per cent by volume of attar of roses.

**ATTAR OF ROSES.** The volatile oil obtained from the petals of *Rosa Damascena* Mill., *R. centifolia* L., or *R. moschata* Herrm.

**SAVORY EXTRACT.** The flavoring extract prepared from oil of savory, or from savory, or both. It contains not less than 0.35 per cent by volume of oil of savory.

**OIL OF SAVORY.** The volatile oil obtained from savory.



**SPEARMINT EXTRACT.** The flavoring extract prepared from oil of spearmint, or from spearmint, or both. It contains not less than 3 per cent by volume of oil of spearmint.

**SPEARMINT.** The leaves and flowering tops of *Mentha spicata* L.

**OIL OF SPEARMINT.** The volatile oil obtained from spearmint.

**STAR ANISE EXTRACT.** The flavoring extract prepared from oil of star anise. It contains not less than 3 per cent by volume of oil of star anise.

**OIL OF STAR ANISE.** The volatile oil distilled from the fruit of the star anise (*Illicium Verum* Hook.).

**SWEET BASIL EXTRACT.** The flavoring extract prepared from oil of sweet basil, or from sweet basil, or both. It contains not less than 0.1 per cent by volume of oil of sweet basil.

**SWEET BASIL, BASIL.** The leaves and tops of *Ocimum basilicum* L.

**OIL OF SWEET BASIL.** The volatile oil obtained from basil.

**SWEET MARJORAM EXTRACT, MARJORAM EXTRACT.** The flavoring extract prepared from the oil of marjoram, or from marjoram, or both. It contains not less than 1 per cent by volume of oil of marjoram.

**OIL OF MARJORAM.** The volatile oil obtained from marjoram.

**THYME EXTRACT.** The flavoring extract prepared from oil of thyme, or from thyme, or both. It contains not less than 0.2 per cent by volume of oil of thyme.

**OIL OF THYME.** The volatile oil obtained from thyme.

**TONKA EXTRACT.** The flavoring extract prepared from tonka bean, with or without one or more of the following: Sugar, dextrose, glycerin. It contains not less than 0.1 per cent by weight of coumarin extracted from the tonka bean together with a corresponding proportion of the other soluble matters thereof.

**TONKA BEAN.** The seed of *Coumarouna odorata* Aublet (*dipteryx odorata* (Aubl.) Willd.).

**VANILLA EXTRACT.** The flavoring extract prepared from vanilla bean, with or without one or more of the following: Sugar, dextrose, glycerin. It contains in 100 cubic centimeters the soluble matters from not less than 10 grams of the vanilla bean.

**VANILLA BEAN.** The dried, cured fruit of *Vanilla fragrans* (Salisb. Ames (*V. planifolia* Andr.)).

**WINTERGREEN EXTRACT.** The flavoring extract prepared from oil of wintergreen. It contains not less than 3 per cent by volume of oil of wintergreen.

**OIL OF WINTERGREEN.** The volatile oil distilled from the leaves of *Gaultheria procumbens* L.

#### "Vanillin and Coumarin Flavor"

An uncolored solution of vanillin and coumarin should not be designated "White Vanilla," because this name implies that the article is a decolorized true vanilla extract. Such a mixture may be called "Vanillin and Coumarin Flavor," if it corresponds in flavoring strength to vanilla extract. This name will not be proper when the mixture is artificially colored, however. Solutions of vanillin, coumarin, and caramel color are classed as imitations (see heading "Imitation Flavors").

#### "Vanilla and Vanillin Flavor"

The name "Vanilla and Vanillin Flavor" implies that approximately as much of the total flavor of the product is due to true vanilla as to vanillin. Such a name should not be applied to an article that owes its flavor chiefly to vanillin. We have found that a standard vanilla extract is equivalent in flavoring strength though not necessarily in flavoring quality, to a seven-tenths of one per cent (0.7 per cent) vanillin solution. Expressed in another way, 1 pound of vanilla beans has a flavoring strength equivalent to about 1½ ounces of vanillin. We also established that 1 part of coumarin is equivalent in flavoring strength to 3 parts of vanillin, that 1 part of heliotropine or piperonal is equivalent in flavoring strength to 2 parts of vanillin, and that a standard tonka extract is equivalent in flavoring strength to a three-tenths of one per cent (0.3 per cent) vanillin solution.

In the light of the foregoing results, it is a simple matter to construct formulas for flavoring products of different strengths that can be legitimately designated "Vanilla and Vanillin Flavor." For example, if a manufacturer desires to make a product of this type equal in flavoring strength to vanilla extract, he should use ½ gallon of vanilla extract (13.35 ounces of beans per gallon) and ½ gallon of seven-tenths of one per cent (0.7 per cent) vanillin solution (0.93 ounce of vanillin per gallon). For a double-strength extract of this type he should dissolve 0.93 ounce of vanillin in 1 gallon of standard vanilla extract. For higher concentration it is necessary to use a concen-



trated vanilla extract or a vanilla oleoresin in order to obtain a proper proportion of true vanilla.

*"Vanilla, Vanillin, and Coumarin Flavor"*

At least 50 per cent of the total flavor of an extract designated "Vanilla, Vanillin, and Coumarin Flavor" should be derived from true vanilla and not more than 50 per cent from the synthetics, vanillin and coumarin. Our organoleptic tests have shown that 1 part by weight of coumarin is equal in flavoring strength to 3 parts by weight of vanillin. Therefore, in order to make 2 gallons of a "Vanilla, Vanillin, and Coumarin Extract" of a strength corresponding to a standard vanilla extract use at least 1 gallon of standard vanilla and 1 gallon or less of a solution of vanillin and coumarin, the flavoring strength of which is equivalent to a 0.7 per cent vanillin solution. The quantities of vanillin and coumarin to be used will depend upon whether it is desired to employ the usual commercial ratio of 5 parts of vanillin to 1 part of coumarin or some other ratio, such as 8:1 or 3:1. For a ratio of 5:1, use 0.560 ounce of vanillin and 0.112 ounce of coumarin per gallon. For a ratio of 8:1, use 0.650 ounce of vanillin and 0.082 ounce of coumarin per gallon. For a ratio of 3:1, use 0.448 ounce of vanillin and 0.150 ounce of coumarin. For a double strength extract, dissolve twice the foregoing quantities of vanillin and coumarin in a gallon of standard vanilla extract. Do not use artificial color; adhere closely to the foregoing proportions of true and synthetic ingredients. Otherwise, do not designate the product "Vanilla, Vanillin, and Coumarin."

*Summary of Relative Flavoring Strengths*

The relative flavoring strengths of the ordinary constituents of imitation vanilla flavors have been determined organoleptically in the laboratories of the Food and Drug Administration and found to be as follows:

One part of vanilla beans is equivalent to 0.07 part of vanillin.

A standard vanilla extract is equivalent to a 0.7 per cent vanillin solution.

A standard tonka extract is equivalent to a 0.3 per cent vanillin solution.

One part of coumarin is equivalent to 3 parts of vanillin.

One part of heliotropine or piperonal is equivalent to 2 parts of vanillin.

*Imitation Flavors*

The labels of imitation food flavors should bear in type of uniform size and promi-

nence, the word "Imitation" and immediately thereafter, the name of the flavor imitated (See Section 403(c)).

The Administration attaches special significance to the presence of caramel color in a solution of vanillin coumarin, and vanilla, or of combinations of two or more of these flavors because the caramel color gives the product the appearance of being a true vanilla extract. Therefore, solutions of these flavors that are artificially colored in imitation of true vanilla extract should be labeled as imitations.

The labels of imitation flavors should bear a list of ingredients including the various flavoring ingredients, as for example, in the case of an imitation vanilla flavor, "Vanillin coumarin, caramel, glycerin, and water." The list of ingredients should preferably be placed in direct conjunction with the name and with the degree of conspicuousness required by Section 403(f) of the Act. The statement of ingredients should not be buried or concealed by including it in unrequired descriptive matter.

Vanilla should not be listed as an ingredient of an imitation vanilla flavor without qualification if it is present in an amount which cannot be readily detected by testing. In this case the vanilla should be listed as a trace of vanilla.

A continuation of the organoleptic tests to which reference has been made, definitely showed that when even so little as 5 per cent of the total flavor of an imitation vanilla extract is true vanilla flavor, the flavor of true vanilla can be detected in the finished article.

It has not been stated that when 5 per cent by volume of true vanilla extract is present, the flavor of true vanilla can be detected. This may be quite a different proposition. The relative volume of solutions of true and imitation ingredients used in the manufacture of a flavor is not regarded as being of particular importance, because these solutions may be of different concentrations. Moreover, there is usually a vast difference between the flavoring value of equal weights of true and imitation flavors. For example, statements such as "98 per cent True, 2 per cent Artificial Flavor" have been commonly used to describe fruit type flavors made by mixing 98 per cent by volume of fruit extract with 2 per cent by volume of a solution of synthetics. Such statements convey the erroneous impression that 98 per cent of the total flavor of the article is due to fruit, whereas, in most cases,



about 98 per cent of the total flavor is due to synthetics. This type of labeling is misleading unless it is employed to describe the percentage of flavor contributed by the ingredients and not merely percentage by volume of ingredients.

It has been indicated that vanilla should not be mentioned without qualification on the label of an imitation vanilla unless at least 5 per cent of the total flavor is due to true vanilla. It has been stated also that one pound of vanilla beans is equal in flavoring strength to  $1\frac{1}{8}$  ounces of vanillin. What then are the proper quantities of vanilla beans and vanillin to employ in order to list vanilla without qualification as an ingredient of an imitation vanilla? It so happens in the case of a standard strength flavor, that 5 per cent by volume of true vanilla extract will produce about 5 per cent of the total flavor. Therefore, one gallon of the finished flavor represents 0.66 ounce of beans and 0.88 ounce of vanilla. In the case of a triple strength extract, that is, an article which has three times the flavoring strength of a standard vanilla, 5 per cent by volume of standard vanilla extract represents only 1.7 per cent of the total flavor. To express the relation in another way, not more than  $21\frac{1}{3}$  ounces of vanillin should be employed to each pound of beans if the flavor of true vanilla is to be detected in the finished products.

The term "VANILLA" in the list of ingredients should not be displayed more prominently on the label of an imitation vanilla extract than the words, "VANILLIN, COUMARIN, CARAMEL COLOR, ETC.," because the impression may be conveyed that more true vanilla is present than is actually the case.

The names of the flavoring ingredients should be listed in the order in which they contribute to the flavor of the article, as, for instance, "VANILLA; COUMARIN AND VANILLA," followed by the specific names of the other ingredients.

#### *Worthless Imitations*

The character of imitation extracts and flavors should be such that they will substantially take the place of the products they imitate. Occasionally, the Administration examines flavors labeled as imitations, and finds them to be artificially colored solutions containing little or no distinctive flavor of any kind. One sample of this kind was contained in a small glass jug which made a very prepossessing package. However, if the housewife should pour the entire con-

tents of the jug into a batch of cake batter, the only effect would be to dilute the material.

#### *Labeling Genuine and Imitation Fruit Flavors and Fruit Sirups*

Fruit flavors used for flavoring sirups and beverages are of a somewhat different type than flavoring extracts used in cooking and their labeling is fully discussed in an article entitled "Labeling of Fruit-type Beverages and Beverage Materials," a copy of which will be sent on request to the Food and Drug Administration, Federal Security Agency, Washington, D. C.

#### *Misleading Containers*

Flavors are classed as misbranded if their containers are so made, formed, or filled as to be misleading (Section 403(d)). Definitely misleading containers can be readily recognized and discarded. In the case of less obviously misleading packages but where the manufacturer has misgivings about the honest appearance of the package the prudent course is to discard it in favor of one of the many types of bottles or other packages about which there can be no question. A bottle may be misleading by reason of paneling, undue thickness of glass, because it is slack filled, etc. In the case of bottles packed in cartons it is possible to have a situation where the bottle may not be deceptive per se but may be too small to fit the carton properly or of a shape so at variance with that of the carton that the size of the carton suggests much more of the product than is actually purchased.

#### *Name and Address of Manufacturer, etc.*

Flavor labels should bear the name and place of business of either the manufacturer or packer or distributor. If the name given is that of the packer or distributor rather than that of the manufacturer it should be qualified by some phrase like "Packed for," "Distributed by," etc.

#### *Quantity of Contents Statement*

Flavors should be labeled with a statement of quantity of contents. The statement should be plain and conspicuous, should be expressed in terms of liquid measure, in terms of the largest unit in the package, and should be accurate.

#### *Listing of Ingredients*

Flavors which are not standardized and which are fabricated from two or more ingredients should be labeled with the common or usual name of each such in-



redient. The flavoring ingredients should be listed first in the order in which they contribute flavor, followed by the specific name of the vegetable gum and other ingredients. Water should be listed when present.

Pending the formulation of standards under the Food, Drug, and Cosmetic Act, the following extracts need not be labeled with a list of ingredients: Lemon and orange extracts containing at least 5 per cent of lemon and orange oil respectively; vanilla extract made from at least 13.35 ounces of vanilla beans per gallon of extract.

#### *Artificial Color*

Only those coal-tar colors may be used in flavors that are from batches of such colors certified by the Food and Drug Administration as harmless and suitable for such use. The law, in dealing with this problem, requires that both coal-tar colors themselves and coal-tar colors mixed with harmless diluents shall be subjected to the certification procedure.

Any harmless vegetable dye may be used in flavors or other food. There is no system of certification in the case of vegetable dyes.

The presence of a certified coal-tar color may be shown on the label by the words, "Artificially colored," "Certified color," or merely "Color added."

Information regarding certification and labeling of coal-tar colors is contained in Service and Regulatory Announcement, S.R.A., F.D.C. 3, which will be sent on request.

The presence of caramel may be declared on the labels of flavors as "Colored with caramel," "Caramel color," or "Artificially colored."

#### *Chemical Preservative*

The presence of benzoate of soda may be declared as "Preserved with 0.1 per cent of benzoate of soda," if that proportion is present, or as "Preserved with benzoate of soda."

#### *Guaranty Statements*

No reference to any kind of guaranty should appear on the labels of flavors unless the basis and sponsorship for the guaranty is so clearly set forth as to leave no doubt that the statement that is made has nothing to do with a guaranty under the Federal Food, Drug, and Cosmetic Act.

#### *Artificial Flavoring*

The use of synthetic flavoring ingredients in a flavor will usually result in causing the flavor to be classed as an imitation. This is especially the case when the flavor is artificially colored. Vanillin and coumarin should always be declared in a manner to show their artificiality or synthetic character.

#### *Where Label Statements Must Appear*

In general, all required information should appear on the main display panel of bottle and carton. If more than one panel is used for display, the required information should appear on each. This statement applies to the name and address of manufacturer, distributor or packer, the quantity of contents, name of the product, list of ingredients when required, declaration of artificial color, added preservative, and imitation character. For qualifications of this general statement see Regulations, Sections 403(e) and (f).

#### *Use of Menstruums Other Than Ethyl Alcohol and Vegetable Oils*

There is no objection to the use of edible vegetable oils such as corn oil and peanut oil, as vehicles for non-alcoholic flavors, provided the oils contain no impurities that might render the products injurious to health and provided suitable labeling is employed.

#### *Glycerin*

There is no objection to the use of the usual small quantities of glycerin in food products provided it is of a purity suitable for food use and provided its presence is plainly declared in the labeling when required by the act.

#### *Other "Alcohol Substitutes"*

A number of chemicals have been proposed for use in place of alcohol in the manufacture of flavors. These so-called "alcohol substitutes" have either been shown to be toxic to such a degree that food flavors containing them would be classed as adulterated under the act, or their freedom from toxic properties has not been demonstrated with that degree of finality which would warrant sanction of their use under all conditions.

#### *Responsibility for Use of Questionable Vehicles or Menstruums*

The responsibility for the use as vehicles in extracts, in place of alcohol, of chemicals that have not been thoroughly investigated



as to their physiological action, must be assumed by the manufacturer. Only those substances found wholesome through adequate investigations by competent pharmacologists should be used.

It should be remembered that the courts have been strict in their interpretation of the law as applied to added deleterious ingredients. The Supreme Court has held in effect that since food is consumed "by the strong and the weak, the old and the young, the well and the sick," any food which because of any added poisonous or other deleterious ingredient may possibly injure the health of any of these, will "come within the ban of the statute."

#### *State Laws*

State laws may contain additional requirements for the labeling of flavors and extracts or different ones than those set forth here. For instance, the Federal Food, Drug, and Cosmetic Act does not require a state-

ment of the proportion of alcohol on the labels of flavoring extracts used exclusively for food purposes, although certain state laws make this requirement. A list of state food officials will be forwarded upon request. Information regarding state laws and regulations should be obtained direct from the state officials.

#### *Approval of Labeling*

Neither the Administration nor the Agency is authorized to approve labels of flavors. If the manufacturers will submit specimens of labels of which they are in doubt as to proper legal form, the Administration will be glad to comment upon them from the standpoint of the act, provided a complete quantitative statement of the composition of the article is also submitted. However, absence of comment should not be construed as approval of the label for the reasons just mentioned.

### **NOTICE TO MANUFACTURERS OF PREPARATIONS OF OVARY**

"Ovarian Extracts" have been found not to contain the known therapeutically and physiologically active constituents of ovary, namely, those having estrogenic and progestational activities. Such inert or essentially inert preparations, when sold as "Ovarian Extract" or under any other designation which implies that such active principles are present, are adulterated and misbranded.

TC-13 [See TC-376]—December 1, 1939

There are on the market drug products in liquid form designated as "Ovarian Extract" or by some similar title. In some instances these products have been found not to contain the known therapeutically and physiologically active constituents of ovary, namely, those having estrogenic and progestational activities. The Food and Drug Ad-

ministration is of the opinion that such inert or essentially inert preparations when sold as "Ovarian Extracts," or under any other designation or under labeling which states or implies that such active principles are present, are both adulterated and misbranded as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

### **WARNING STATEMENTS FOR DRUG PREPARATIONS**

Memorandum listing a number of drug preparations with indications concerning the nature of warning statements which are not subject to adverse criticism.

TC-14—Reprinted November 1, 1940  
Chiefs of Districts and Stations:

With our letter of December 29, 1939, we forwarded to you a memorandum listing a number of drug preparations with indications concerning the nature of warning statements which are not subject to adverse criticism for the present.

The necessity for another reprint of this memorandum has provided a convenient opportunity to make a few minor changes in the interest of clarity and editorial elegance.

In no instance has the force and effect of the warning statements been changed. You will also note that we have provided an index to facilitate the use of this material.

#### **Index**

Acetanilid .....	XVI
Acetophenetidin .....	XVII
Ammonia .....	XXVI
Anthelmintics .....	XV
Carbon tetrachloride (1)	
Tetrachlorethylene (2)	



Aspidium (male fern) (3)		Iodine or Iodides	X
Santonin (4)		Irritants	I, XXVI
Chenopodium oil (5)		Kerosene	XXVI
Thymol (6)		Laxative drugs	I
Antipyrine	XVIII	Male fern	XV
Arnica	XXVI	Mercury	XXV
Arsenic preparations	XXI	Methyl salicylate	XXVI
Aspidium (male fern)	XV	Mineral oil	V
Atropine and related drugs	IX	Mustard	XXVI
Bromides	XIX	Nose drops	VII
Cantharides	XXVI	Nux Vomica	XIV
Capsicum	XXVI	Oleoresins	VIII
Carbon tetrachloride	XV	Ouabain	XXVIII
Carbolic acid	XI	Pepper	XXVI
Castor oil	II	Phenolphthalein	III
Cathartic drugs	I	Quinine	XXII
Cayenne pepper	XXVI	Resins	VIII
Chenopodium oil	XV	Roughage material	IV
Chlorates in mouth washes and gargles	XX	Rubefacients	XXVI
Chloroform	XXVI	Santonin	XV
Chrysarobin	XXVII	Scopolamine	IX
Cinchonidine	XXII	Silver preparations	XXIII
Cinchonine	XXII	Sodium perborate	VI
Coughs	XXIV	Sprays, nose	VII
Cresols	XII, XIII	Squill	XXVIII
Creosote	XII, XIII	Strophanthus	XXVIII
Digitalis or related drugs	XXVIII	Strychnine	XIV
Douches	XII, XXV	Surface application	XXVI
Ether	XXVI	Tetrachlorethylene	XV
Goa powder	XXVII	Thymol	XV
Guaiacol	XII, XIII	Turpentine oil	XXVI
Hyoscyamine	IX	Urinary tract	VIII
Inhalants	VII	Volatile oils	VIII

### Memorandum on Warning Statements Under Section 502(f)(2)

**I. Cathartic or laxative drugs** (except castor oil and phenolphthalein) which act as irritants to the gastro-intestinal tract or stimulate intestinal peristalsis:

"Warning: Not to be used when abdominal pain (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.

"Frequent or continued use of this preparation may result in dependence on laxatives."

#### II. Castor oil:

"Warning: Not to be used when abdominal pain (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.

"Frequent or continued use of this preparation may result in dependence on laxatives.

"Do not use during pregnancy except on competent advice."

#### III. Phenolphthalein:

"Warning: Not to be used when abdom-

inal pain (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.

"Frequent or continued use of this preparation may result in dependence on laxatives.

"Important: If a skin rash appears, discontinue use."

**IV. Roughage materials** (so-called) intended for use in constipation:

"Important: All varieties of constipation are not benefited by this preparation. It should be particularly avoided in cases such as spastic constipation in which abdominal discomfort or pain may be present."

#### V. Mineral oil for oral administration:

"Important: Do not take directly before or after meals."

NOTE: There will be no objection to an explanation added to the above statement indicating that mineral oil may interfere with the absorption of pro-vitamin A, carotene, and other substances.



**VI. Sodium perborate** intended for local use in the mouth and throat:

"Warning: This preparation may cause irritation and inflammation of the gums, tongue and mucous membranes of the mouth. It should be discontinued at the first sign of irritation or soreness. In case of doubt, consult your physician or dentist."

**VII. Nose drops, inhalants and sprays:**

1. Those that contain oil as a vehicle or base:

"Caution: Frequent or excessive use of this preparation may cause injury to the lungs. Do not use at all in infants and younger children except on competent advice."

2. Those that contain ephedrine, epinephrine, amphetamine (benzedrine), propan-drine, neosynephrin and other vaso-constricting drugs of similar activity:

"Caution: Frequent or continued use may cause nervousness, restlessness or sleeplessness. Individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble should not use this preparation except on competent advice."

NOTE: The above warning may also be appropriate for the same ingredients intended for internal administration. However, amphetamine (benzadrine) indiscriminately distributed and intended for its systemic effect is dangerous.

**VIII. Resins, oleoresins, and volatile oils** intended for their effect upon the urinary tract:

"Warning: If disturbance of the stomach or bowels or skin rash is noticed, discontinue use."

**IX. Atropine, hyoscyamine, scopolamine** and pharmacologically related drugs:

"Caution: Frequent or continued use of this preparation should be avoided. Use cautiously if dryness of the throat occurs; discontinue if rapid pulse or blurring of vision appears.

"Warning: This preparation should not be taken by elderly people except on competent advice."

**X. Iodine or iodides:**

"Warning: Do not use in cases of lung disease, chronic cough or goiter (thyroid disease) except upon the advice of a physician.

"If a skin rash appears, discontinue use."

**XI. Carbolic acid** in preparations for external application:

NOTE: Products containing more than 2 per cent of carbolic acid are not considered safe for indiscriminate distribution.

"Warning: When applied to fingers and toes, do not use a bandage.

"Apply according to directions for use, and in no case to large areas of the body."

**XII. Cresols, creosote, guaiacol** and similar substances intended for use as douches:

NOTE: Preparations intended for use after dilution should bear adequate directions for preparing solution and thorough mixing before pouring into douche bag.

"Warning: The use of solutions stronger than those recommended may result in severe local irritation or burns or serious poisoning."

**XIII. Cresols, cresote, guaiacol** and similar substances intended for surface application:

"Warning: Do not apply to large areas of the body."

**XIV. Nux vomica and strychnine:**

"Warning: Do not take more than the dosage recommended. Frequent or continued use is to be avoided and its use for children and elderly persons may be especially dangerous."

**XV. Anthelmintics:**

NOTE: The following preparations in therapeutically potent doses are not safe for indiscriminate distribution and should only be used under the direct supervision of a physician:

**1. Carbon tetrachloride:**

NOTE: Specific adequate directions for administration of a saline cathartic after use of this drug should be given.

"Warning: Avoid castor oil or other preparations or foods containing oil or fat while this drug is being administered. The use of this preparation in debilitated children and persons addicted to alcohol is dangerous."

**2. Tetrachlorethylene:**

NOTE: Specific adequate directions for the administration of a saline cathartic should be given.

**3. Aspidium (Male Fern):**

NOTE: Specific adequate directions for administration of a saline cathartic should be given.

"Warning: Avoid castor oil or other preparations or foods containing oil or fat



while this drug is being administered."

#### 4. Santonin:

"Very important: Shake vigorously before using. Failure to do so may result in serious injury.

"Caution: The use of more than the prescribed dose is dangerous.

"Avoid castor oil or other preparations or foods containing oil or fat while this drug is being administered.

"The prescribed dose should not be repeated within 7 days."

#### 5. Chenopodium oil:

NOTE: Specific adequate directions for administration of a cathartic, preferably castor oil, should be given.

#### 6. Thymol:

NOTE: Specific adequate directions for administration of a saline cathartic should be given.

"Warning: Avoid alcohol or any preparation containing alcohol before or during administration of this drug."

#### XVI. Acetanilid:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug. Do not take more than the dose recommended. Not to be given to children."

#### XVII. Acetophenetidin:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances.

"Do not take more than the dosage recommended."

#### XVIII. Antipyrine:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances.

"Do not take more than the dosage recommended."

#### XIX. Bromides:

"Warning: Frequent or continued use may lead to mental derangement, skin eruptions or other serious effects.

"Do not take more than the dosage recommended.

"Not to be taken by those suffering from kidney disease."

**XX. Chlorates** in mouth washes and gargles:

"Caution: Avoid swallowing."

**XXI. Arsenic preparations** except those employed as chemotherapeutic agents for specific diseases such as syphilis, amebic dysentery, etc.:

"Caution: Continued or prolonged use may result in serious injury."

**XXII. Quinine, conchonine and cinchonidine:**

"Caution: Discontinue use if deafness, skin rash, visual disturbances (eye trouble) or other serious symptoms appear."

#### XXIII. Silver preparations:

"Caution: Prolonged or frequent use of this preparation may result in permanent discoloration of the skin and mucous membranes."

**XXIV. Preparations sold under representations relating to coughs due to colds:**

"Important: Persistent coughs may indicate the presence of a serious condition. Do not use this preparation if there is a high fever or the cough has persisted for 10 days without securing medical advice."

#### XXV. Mercury:

1. Intended for administration by mouth or as a douche:

"Warning: The prolonged or frequent use of this preparation or the use of amounts in excess of the prescribed directions may cause serious mercury poisoning."

2. Intended for application to the skin:

"Warning: This preparation may cause irritation of the skin, and the application to large areas may cause serious mercury poisoning."

NOTE: This warning is not applicable to mercury bleach creams. See Notice to Manufacturers of Mercury Bleach Creams of May 13, 1939.

**XXVI. Rubefacients and counter-irritants** such as ammonia, arnica, cantharides, cayenne pepper (capsicum), chloroform, ether, kerosene, methyl salicylate, pepper, mustard, or turpentine oil intended for surface application:

"Caution: This preparation may cause excessive irritation of the skin, particularly if applied with rubbing. Avoid getting it into the eyes or on mucous membranes."

#### XXVII. Goa Powder and chrysarobin:

"Caution: The use of this product over large skin areas may cause kidney irritation.

"Warning: Keep away from the eyes."



**XXVIII. Digitalis, strophanthus, and pharmacologically related drugs in therapeutically effective proportions:**

NOTE: Potent doses of these drugs have cumulative action and may lead to disastrous effects upon the heart and circulation. They should be used only under the direct supervision of a qualified physician.

"Caution" should be exercised in using this preparation, particularly if the patient has had digitalis, squill, strophanthus, ouabain or similar drug within the preceding three weeks.

"The appearance of anorexia (loss of appetite), nausea, vomiting, headaches or heart

irregularities (palpitation) is often an early sign of full digitalization or overdosage. When such symptoms appear, do not continue the use of this preparation without consulting the physician."

or

"Caution: This drug requires careful and accurate dosage under the guidance of a physician. The appearance of anorexia (loss of appetite), nausea, vomiting, headaches or heart irregularities (palpitation) often indicates either full digitalization or overdosage. When such symptoms appear, do not continue to use this preparation without first consulting the physician."

#### DECLARATION OF THE PRESENCE OF EGG SUBSTANCES IN BAKERY PRODUCTS

Food and Drug Administration will not take exception to the unqualified term "eggs" in the ingredient list on the label for a baked product whether dried whole eggs, frozen whole eggs, or liquid whole eggs are used. Similarly, the term "egg yolk" may cover the use of dried egg yolk, liquid egg yolk, or frozen egg yolk as ingredients in baked products. The same applies also to the use of the term "egg white" to cover dried egg white (dried egg albumen), liquid egg white, or frozen egg white.

TC-15—February 9, 1940

Response to communication from correspondent who feels that inequities will result if Section 403(i)(2) should be interpreted as requiring a label declaration of the ingredient, dried eggs, in bakery products as "dried eggs" and a label declaration of the ingredient, frozen eggs, merely as "eggs."

"The representatives of the Department with whom you discussed the situation pointed out, I am sure, the basic principles of labeling necessary to insure a distinction between articles of different identity. They discussed the difference in identity between liquid eggs and dried eggs, due to the evaporation of moisture from the original liquid eggs, as distinguished from the mere physical change, due to the change in temperature, in the freezing of liquid eggs. We recognize, however, the force of the argument which may be advanced that when liquid eggs are used as an ingredient in a bakery product the moisture is evaporated and there is therefore, no significant difference in the finished baked product between these two types of egg ingredients.

"After careful consideration, we have reached the conclusion that to all intents and purposes three types of egg ingredients—dried egg, liquid egg, and frozen egg—have, in the finished baked product, lost the characterizing differences of the original egg products. Therefore, we will not take exception to the unqualified term "eggs" in the ingredient list on the label for a baked product whether dried whole eggs, frozen whole eggs, or liquid whole eggs are used. Similarly, the term "egg yolk" may cover the use of dried egg yolk, liquid egg yolk, or frozen egg yolk as ingredients in baked products. The same applies also to the use of the term "egg white" to cover dried egg white (dried egg albumen), liquid egg white, or frozen egg white. Of course, if it should develop that these methods of declaring egg ingredients in baked products result in withholding information from the consumers to which they are entitled under the Act, it would then be necessary to rescind this opinion, and you and the industry would be so notified."



**MINERAL OIL COATING—APPLES**

Some apple packers, in order to retard decay and evaporation, have applied a minute film of mineral oil to the skin of the fruit. Minute amounts of mineral oil are, of course, not harmful, but we believe it in the public interest to discourage a growing disposition to add mineral oil to a wide variety of foodstuffs.

No investigation has been made with respect to any practice of applying paraffin wax to apples.

TC-16—February 9, 1940

"We are not familiar with any practice of applying paraffin wax to apples. Some apple packers have resorted to a process of treating apples which is designed to retard decay and evaporation. This process as we understand it involves the application of a minute film of liquid mineral oil to the skin of the fruit. The Department's interest in this matter from the standpoint of the requirements of the Acts we enforce has been

to advise against the use of any treatment which leaves any amount of mineral oil on the fruit. Minute amounts of mineral oil are, of course, not harmful but we have believed it in the public interest to discourage a growing disposition to add mineral oil to a wide variety of foodstuffs. We have made no investigation which would permit us to express an opinion as to the advantages which might accrue from the use of some treatment such as you propose."

**BULK SHIPMENTS OF AGAR-AGAR AND ISINGLASS NOT REGARDED AS "IN PACKAGE FORM"**

Pending further consideration, action will not be taken on agar-agar or isinglass imported in large bales solely on ground that they do not contain the labeling required of packages under Section 403(e) or Section 502(b).

TC-17—February 9, 1940

Are importations of agar-agar or isinglass in bales or other so-called bulk forms considered to be "in package form" within the intent of Sections 403(e) or 502(b) of the Act?

"Agar-Agar and isinglass are products which, to some extent, have been used as drugs, and, to some extent, have been used in food products.

"We have not had opportunity to give suitable consideration to the question as to whether or not agar-agar and isinglass as imported in large bales are packages within the intent of Sec. 403(e) or Sec. 502(b) of the Act and, therefore, should be marked with a statement of net weight and other

statements provided in these paragraphs. The question raised is one concerning which there may be reasonable doubt. Pending such time as this matter may be later given adequate consideration, action will not be taken on agar-agar or isinglass so shipped solely on the ground that they do not contain the labeling required of packages under Section 403(e) or Section 502(b), nor will such action be taken except and until suitable notice to the contrary has been given to the trade. This, of course, should not be considered as relieving the product from any other markings or requirements which may be made under Sections 403 and 502 of the Act. \* \* \*

**AGAR-AGAR IN CANDY**

Agar-agar may be employed in candy (confectionery) provided it does not result in the concealment of damage or inferiority or make the article appear to be of better value than it is.

TC-18—February 9, 1940

Do Federal laws govern the use of agar-agar in the manufacture of candy?

"Confectionery shipped within Federal jurisdiction must meet all of the provisions of the Food, Drug, and Cosmetic Act. There is no specific mention of agar-agar in the law in connection with its use in candy, but its use would be controlled by the general

adulteration and misbranding provisions. In brief, it may be employed provided it does not result in the concealment of damage or inferiority or make the article appear to be of better value than it is. It should contribute no deleterious substance to the confectionery, and candy containing it should be labeled in accordance with the labeling provisions of Section 403."



**CHARCOAL IN CONFECTIONERY**

The Act will not prohibit the use of charcoal in confectionery if it is of a suitable degree of purity, provided that the confectionery to which it is added is not thereby adulterated under Section 402 and is labeled as required by Section 403.

TC-19—February 9, 1940

"The provisions of the Food, Drug, and Cosmetic Act will not prohibit the use of charcoal in confectionery provided it is of a suitable degree of purity, provided the con-

fectionery to which it is added is not thereby adulterated in any of the ways set forth in Section 402, and provided the confectionery is labeled as required by Section 403."

**LAXATIVES—"HERBAL" PREFERRED TO "VEGETABLE"**

The term "vegetable" is apt to convey the idea of ordinary garden vegetables. The term "herbal" is not subject to the same criticism.

TC-20—February 9, 1940

Commenting on labeling for proprietary laxative product.

"The term 'vegetable' is apt to convey the idea of ordinary garden vegetables. The term 'herbal' is not subject to the same criticism."

**CORN REMOVERS AND MEDICAL CORN PADS CLASSED AS DRUGS**

Liquid corn removers and medical corn pads are drugs under definition contained in Section 201(g).

TC-21—February 9, 1940

Are liquid corn removers and medical corn pads classified as cosmetics or drugs?

"The definition of the term 'cosmetic' is given in Section 201(i) of the act and the

definition of the term 'drug' in Section (g). It will be apparent from a study of these definitions that both of the products are drugs as that term is used in the act."

**PROPER DECLARATION OF QUANTITY OF CONTENTS**

Statements such as "Contents 2 Ounces" should be avoided. If product is subject to the requirement that the amount be declared in weight, statement may read "Contents 2 Ounces Avoirdupois" or abbreviation "avoir." or "Net Weight 2 Ounces." When fluid measure is meant, the statement may read "Contents 2 Fluid Ounces."

TC-22—February 9, 1940

Correspondent inquires if the quantity of contents statement on a package of cosmetic may be "Contents 2 Ounces" or must be "Net Weight 2 Ounces"; also whether "Av. Ounces" necessary or whether "Ounces" sufficient.

"An ambiguity exists in the unqualified expression 'Ounces' for the reason that it may be interpreted to mean either fluid ounces or avoirdupois ounces. Therefore, \* \* \* we have consistently pointed out that

statements such as 'Contents 2 Ounces' should be avoided \* \* \*. If the product is subject to the requirement that the amount be declared in weight, the statement may read 'Contents 2 Ounces Avoirdupois' (or the abbreviation 'Avoir.') or 'Net Weight 2 Ounces.' Either statement removes the ambiguity. When fluid measure is meant, the statement may read 'Contents 2 Fluid Ounces.' We do not favor the abbreviation Av. for avoirdupois, since it may be confused with the abbreviation for the word 'average.'"

**DRUG CONTAINERS, QUANTITY OF CONTENTS**

Bottle of 15 c.c. capacity with graduations at 10 c.c. and 15 c.c. would violate Section 502(i)(1) if only  $\frac{2}{3}$  full, notwithstanding that the label clearly stated the volume of contents.

TC-23—February 9, 1940

Correspondent requests interpretation of

Section 502(i)(1) as applied to a bottle of 15 cubic centimeters capacity having gra-



duation marks of 10 and 15 cubic centimeters respectively. Would this section of Act be violated if such a container were shipped within the jurisdiction of the Act containing 10 cubic centimeters of a liquid preparation, the label clearly stating the volume of contents?

"Under the conditions described, the preparation would be marketed in a container two-thirds filled. It is our opinion that such a container would be regarded as deceptive even though a proper declaration of the volume appeared upon the label."

### DEPILATORIES (MAY BE DRUGS OR COSMETICS)

Cream depilatories, as ordinarily represented, would be cosmetics, and label would not have to bear a statement of the active ingredients. Such preparations may be represented in such a way, however, as to class them as drugs.

TC-24—February 9, 1940

"Cream depilatories as ordinarily sold and represented would, in our opinion, be cosmetics. It is, however, conceivable that such preparations may be represented in

such a way as to class them as drugs. If the preparation is in fact a cosmetic, it will not be necessary for the label to bear a statement of the active ingredients."

### AMPULS—NEED FOR LABEL DECLARATION OF PRESERVATIVES

As general rule, any agent which was added to a drug to serve as a preservative should be declared and the quantity given, so as to enable the physician to form a definite opinion of the limits of administering the article with a view to avoiding an excess amount of the preservative.

TC-25—February 9, 1940

"As a general rule any agent which was added to a drug to serve as a preservative should be declared and the quantity given, so as to enable the physician to form a definite opinion of the limits of administering the article with a view to avoiding an ex-

cess amount of the preservative. Some solutions are injected intravenously in quantities as high as 500 to 1000 ccs. and the preservatives used in such preparations become of much importance to the practitioner."

### DEODORANT POWDER

If action of preparation is to stop perspiration, such a product would be a drug. If, however, the only action of the deodorant powder is to absorb the perspiration or to mask its odor, it would probably be a cosmetic.

TC-26—February 9, 1940

"\* \* \* If the action of the preparation is to stop perspiration, such a product would in our opinion be a drug; if, how-

ever, the only action of the deodorant powder is to absorb the perspiration or to mask its odor, it would probably be a cosmetic. \* \* \*"

### USE OF TITANIUM DIOXIDE IN COSMETICS

Whether or not titanium dioxide is suitable for use in cosmetics depends on whether its use will result in the finished product being adulterated under Section 601. No numerical tolerances have been set for lead and arsenic in cosmetics.

On the basis of present knowledge, no objection would be taken to the use in cosmetics of titanium dioxide which contained less than 20 parts per million of lead (as Pb), and less than 2 parts per million of arsenic (as  $As_2O_3$ ).

TC-27 (See also TC-170)—

February 9, 1940

Request for information about the use in a cosmetic of 3 per cent "Titanox A", a product which you state contains 100 p.p.m. of lead (one part per 10,000).

"In regard to the use of titanium dioxide:

No regulations have been issued specifically limiting the lead content of titanium dioxide itself. Whether or not titanium dioxide is suitable for use in cosmetics depends entirely upon whether or not the use of such preparation will result in the finished product being adulterated within the meaning



of Section 601 of the statute. The responsibility for compliance with the statute, however, rests entirely upon the manufacturer. No numerical tolerances have been set for lead and arsenic in cosmetics, nor can such tolerances be set at present. \* \* \*

\* \* \* On the basis of our present

knowledge, however, we would not be disposed to object to the use in cosmetics of titanium dioxide which contained less than 20 parts per million of lead (as Pb) and less than 2 parts per million of arsenic (as  $\text{As}_2\text{O}_3$ ), these being the limits permitted for D&C coal-tar colors."

#### ANCHOVIES, SPRATS, HERRING TIDBITS, WEIGHT OF SAUCE

If the spiced sauce used in packing Swedish Anchovies, Sprats and Herring Tidbits is edible and is usually eaten by the consumer, the net weight statement on the containers may include both the weight of the fish and weight of the sauce.

TC-28—February 9, 1940

"If the spiced sauce used in packing Swedish Anchovies, Sprats and Herring Tidbits is of such a character as to be edible and is, as a matter of fact, usually

eaten by the consumer, then the net weight statement on the containers may include both the weight of the fish and the weight of the sauce."

#### TRADE (BRAND) NAMES, BARBITURIC ACID DERIVATIVES

Trade names will not be recognized in connection with the declaration of common names, although regulations not yet issued under Section 502(d). If "Luminal" is referred to parenthetically after phenobarbital, and the reference does not abridge the understanding of the nature of the preparation, no violation will be regarded as having occurred.

TC-29—February 9, 1940

Discussion at interview of the use, in label statements requiring common name of drug, of trade names such as "Luminal" for phenobarbital:

"Although regulations under Section 502(d) have not yet been issued, the visitor was told that undoubtedly the Secretary would not recognize trade names in con-

nection with the declaration of common names. The visitor was further told that if he referred to Luminal parenthetically after phenobarbital and that if the reference did not in any way abridge the understanding of the nature of the preparation by the consumer or the physician, no violation would be regarded as having occurred."

#### ARTICHOKES, CITRIC ACID IN

The label of canned artichokes, to which one-half of one percent citric acid has been added to change the hydrogen concentration of the commodity, will meet the requirements of the Act if it bears a statement listing the ingredients as artichokes and citric acid, since citric acid, under such circumstances, is not regarded as an artificial preservative.

TC-30—February 9, 1940

Should the label of canned artichokes to which one-half of one per cent citric acid has been added state that the citric acid is a chemical preservative? The citric acid is added to change the hydrogen ion concentration of the commodity so that processing at the temperature of boiling water will suffice. If the citric acid is not added, a longer processing at higher temperature is necessary, which destroys the texture of the commodity. To some extent, citric acid

does change the flavor of the commodity.

\* \* \* Our position will be that the label of the article will be regarded as meeting the requirements of the Act if it bears a statement listing the ingredients as artichokes and citric acid, since we do not regard the citric acid added under these circumstances as an artificial preservative. Preservation of the article is accomplished by canning, and after it is removed from the can the citric acid does not act as a preservative."



**ALIMENTARY PASTES, LABELING**

To the extent to which alimentary pastes such as spaghetti, pastina, etc., apply only to physical shapes rather than to identity, and to the extent that they are untranslatable, Administration not disposed to feel that the appearance of such names on a label which is otherwise all in English will require the appearance of the mandatory label information in the foreign language required by paragraph (c) of regulation issued under Section 403(f).

TC-31—February 9, 1940

Interpretation to be placed upon paragraph (c) of the regulation under Section 403(f) in connection with the use of such terms as spaghetti, spaghettoni, pastina, puntine, lasagne, lasagnini, vermicelli, bucatini, zupolini, occhi di bue, fettuccine, farfalline, stelline, alfabeto, etc., indicative of a definite type of alimentary paste, since translation in English is not only practically impossible, but if attempted would

sometimes lead to ludicrous, if not outright misleading, results.

"To the extent to which these terms apply only to physical shapes of the different alimentary pastes rather than to their identity, and to the extent to which they are untranslatable, we are not disposed to feel that the appearance of such names on a label for an alimentary paste which is otherwise all in English will necessitate the appearance on that label of the mandatory label information in the foreign language."

**ANTIPASTO (REGARDED AS COMMON NAME)**

Antipasto, an appetizer consisting of mixed vegetable and fish products, may be accepted as the common name of the product and meeting the requirements of Section 403(i)(1). A label declaration in general terms that the article consists of "Preserved fish and vegetable appetizer", or some similar expression, is not considered sufficient to meet the further statutory requirement that in case of foods fabricated from two or more ingredients, the common or usual name of each ingredient should be announced.

TC-32—February 9, 1940

"This commodity is more or less well known to those of Italian extraction as an appetizer consisting of mixed vegetable and fish products, and has been sold in our markets for many years under the name of 'Antipasto.' It is believed that the expression has acquired a definite meaning and it is the opinion of the Administration that the word 'antipasto' may well be accepted as the common name of the product and meeting the requirements of Section 403(i)(1) of the statute. A label declaration in general terms that this article consists of 'Preserved fish and vegetable appetizer' or some similar expression, is not considered sufficient to meet the further statutory requirement that in case of foods fabricated from two or more ingredients the common or usual name of each such ingredient should be announced. To comply with the letter and spirit of the Act, a definite statement of constituents named individually

would be expected. You understand, of course, that this would not include any constituents in the nature of spices or flavorings, which need not be listed individually.

"You point out that because of the size and the shape of containers in which this article is packed it may be impossible to list all of the ingredients on the principal label. It is well known that antipasto is not packed in as large containers as are many other food commodities, but the Administration is not persuaded that the containers are so small as not to admit of inscription with the mandatory information on the portion of the label or package usually exhibited to the consumer. If necessary, the manufacturer should modify his labels by reducing the size of, or removing entirely other display matter heretofore appearing on the labels so that sufficient space may be available to incorporate in plain and conspicuous manner the information required under Section 403."

**BLUEBERRIES, HUCKLEBERRIES**

The Administration has not instituted action against canned blueberries labeled as huckleberries when sold in those sections where the name "Huckleberries" is used and understood by the consumer.



TC-33—February 9, 1940

"Botanically, huckleberries and blueberries belong to the same family, but local usages of the two names have developed which have become a guide in the labeling of the canned product, which is in most,

if not all, cases blueberries. The Administration has not instituted action, therefore, against canned blueberries labeled as huckleberries when sold in those sections of the country where the name 'Huckleberries' is used and understood by the consumer."

### BAY RUM

The National Formulary does not recognize "Bay Rum" as a synonym for "Compound Spirit of Myrcia." Any action taken by Administration concerning bay rum would be based upon the general understanding of what constitutes this product.

TC-34—February 9, 1940

Does the Administration consider bay rum as a National Formulary article?

"Only one official preparation (Spiritus Myrciae Compositus) is produced from Oleum Myrciae (oil of bay). The National

Formulary does not recognize 'Bay Rum' as a synonym for 'Compound Spirit of Myrcia.'

"Any action taken by this Administration concerning bay rum would be based upon the general understanding of what constitutes this product."

### GUM BENZOIN, TOXICITY OF

No objection has been taken to use of gum benzoin in food in the usual small proportions, but when it is not a normal constituent its presence should be plainly and conspicuously declared on the label.

TC-35—February 9, 1940

"No objection has been made to the use of gum benzoin in food in the usual small proportions, but when it is not a normal

constituent of a food mixture, its presence should be plainly and conspicuously declared on the label."

### BARLEY SUGAR, BARLEY SUGAR CANDY

The term barley sugar is being loosely applied to a product which is not now prepared even in part from barley. Administration, therefore, is inclined to discourage the use of the terms barley sugar and barley sugar candy.

TC-36—February 9, 1940

"The technical information that we have regarding the identity and method of manufacture of barley sugar candy is meager. Available information indicates that when sugar is heated to 160°C. (320°F.) it melts without losing in weight, and congeals on cooling, to a transparent amorphous yellowish mass which becomes gradually opaque on the surface from the formation of minute crystals, and that the resulting product is sometimes referred to as barley sugar. A second source of information states that when rock candy is heated to 185°C. (365°F.), it melts into a viscid, colorless liquid, which on being suddenly cooled forms a transparent mass called barley sugar.

"It is apparent that the term barley sugar is being loosely applied to a product which is not now prepared even in part from barley. We doubt that the term has a derived meaning which would make it understandable to the purchaser, although it may be understood by sugar technologists. We are therefore inclined to discourage the use of the terms barley sugar and barley sugar candy as it is proposed to use them, since they appear to be ambiguous. However, we have made no investigation of consumer understanding of these terms and can advise you only that the responsibility for their use rests upon the manufacturer of the products."

### CHICORY IN BAGS, QUANTITY OF CONTENTS STATEMENT

In view of non-uniformity in size of sacks of bulk shipments of chicory, Administration not disposed to regard sacks of chicory, under circumstances presented, as food in packages and they need not, therefore, bear the net weight statement.



TC-37—February 9, 1940

Application of the Act to bulk shipments of chicory, concerning particularly the statement of net weight on bags which in any one consignment may range from 140 to 160 pounds. When customer orders chicory from the warehouse, the bags are weighed by the warehouse before delivery, and it is the custom of the trade to order a certain number of bags of chicory and not a specific number of pounds. The customer is billed with so many bags weighing so many pounds.

"In view of the non-uniformity in size of the sacks and the fact that the chicory is

sold by the pound, we are not disposed to regard such sacks of chicory under these circumstances as food in packages and they need not, therefore, bear the net weight statement.

"You also ask whether billing gross for net is permissible. The Food, Drug, and Cosmetic Act does not specifically cover the question of billing gross for net. Of course, in any case, the purchaser who orders a certain number of pounds of chicory would, we assume, expect to get that number of pounds of chicory exclusive of the weight of the bags. \* \* \*"

### ANCHOVIES (FILLETS IN OLIVE OIL)

Relative to labeling "Fillets of Anchovies with capers in pure olive oil," Administration not disposed to insist that label carry the statement "With Added Salt" where the anchovies used are salt anchovies from which the salt has been washed prior to packing in olive oil.

TC-38—February 9, 1940

"Relative to the labeling, 'Fillets of Anchovies with capers in pure olive oil,' we are not disposed to insist that the label carry

the statement "With Added Salt" where the anchovies used are salt anchovies from which the salt has been washed prior to packing in olive oil."

### FACIAL TISSUE, PAPER NAPKINS

Facial tissue and paper napkins, when used solely for wiping purposes, are not subject to the provisions of the Act.

TC-39—February 9, 1940

What is the status of paper napkins and facial tissue under the Act?

"This Administration does not regard articles of this type when sold solely for wiping purposes as subject to the provisions of the Act. You made particular mention of the exclusion of soap from the classifi-

cation of cosmetic. We \* \* \* direct your attention to the definition of the term 'cosmetic' which appears in Section 201(i). You will note that the law passed by Congress excluded soap from this definition. This Administration has no authority to broaden the terms of the Act by exempting other cosmetics."

### BABY OIL

Unless some claim is made for baby oil which will classify it as a drug, under Section 201(g), the product will be regarded as a cosmetic.

TC-40—February 9, 1940

"\* \* \* Baby oils are ordinarily used solely for cleansing purposes and the label submitted to you does not recommend any other use for the product. Unless some

claim is made for the article which will classify it as a drug, as this term is defined in Section 201(g) of the Act, your product will be regarded as a cosmetic."

### RUBBER GLOVES

Rubber gloves sold for use by surgeons are therapeutic devices. Rubber gloves intended for household use are not regarded as therapeutic devices unless they are labeled or otherwise offered for use in a way which renders them a device under Section 201(h).



TC-41—February 12, 1940

Correspondent inquires if it is necessary to label surgical and household rubber gloves in any manner in order to comply with the provisions of the Act.

"Rubber gloves sold for use by surgeons are, in our opinion, therapeutic devices because they are used both to protect the surgeon, himself, and to protect the patient. You will note from a careful study of Section 502 of the \* \* \* Act \* \* \* that the only information which will be required to appear on the label of rubber gloves is a

statement of quantity of contents and the name and address of the manufacturer, packer, or distributor.

"Rubber gloves intended for household use, on the other hand, we do not regard as therapeutic devices unless they are labeled or otherwise offered for use in a way which renders them a device as this term is defined in Section 201(h) of the Act. We do not believe that the use of such gloves by the housewife to keep her hands out of dish-water would bring them within the purview of the law."

### CAMPBOR ICE

An article containing gum camphor, beeswax, paraffin, and mineral oil will be a cosmetic if it is called "Camphor Ice" and is offered for softening the lips, hands, and roughened skin.

TC-42—February 12, 1940

Correspondent inquires if an article containing gum camphor, beeswax, paraffin, and mineral oil is to be classified as a drug or as a cosmetic, if it is called "Camphor Ice" and is offered for softening the lips, hands, and roughened skin.

"It is our opinion that an article of this composition, bearing merely the claims quoted, will be a cosmetic as this term is defined in the Federal Food, Drug, and Cosmetic Act."

### POSTPONEMENT REGULATION—CARTONS AND LITHOGRAPHED LABELS

If cartons and lithographed labels are so designed as to require further imprinting, the manufacturing process was not completed prior to February 1, 1939, and they would not qualify for the time extension.

TC-43—February 12, 1940

Correspondent states that another important field for economic salvage not directly included in the regulation under the Lea amendment to the Federal Food, Drug, and Cosmetic Act is encountered in printers' stocks of stock design cartons and labels manufactured and held in stock for no definite user and subsequently imprinted for different users.

"\* \* \* You will note that the amendment itself considers for extension only those cartons and lithographed labels which were manufactured prior to February 1, 1939. If they are designed in such a way that they require further imprinting before the purchaser can use them, even under the old Act, it is our opinion that the manufacturing process had not been completed prior to

February 1, 1939. Therefore, we do not believe that they would qualify for the time extension. However, it appears to us that in many cases the printer can devise a means of temporarily imprinting or applying stickers to these cartons and labels in such a manner that would satisfy the requirements of all the labeling provisions of the new Act."

"\* \* \* In view of the purpose of the amendment to obviate the loss of valuable stocks of labels, we do not construe the words 'held by' in Section 9.01(2) of the regulation in the narrow sense of actual physical possession by the owner. If they were made for you before February 1, 1939, and are still intended for use by you, it is immaterial so far as the regulation is concerned where you store them."

### CITRIC ACID (CALCIUM CITRATE), ARSENIC, LEAD

Administration is of opinion that it is possible practically to eliminate lead and arsenic from citric acid. Therefore, it does not appear that any regulation fixing a tolerance under Section 406 need be promulgated, and Section 402(a)(2) would apply.



TC-44—February 12, 1940

Request information on lead and arsenic tolerances in calcium citrate to be used for food purposes.

"We appreciate your desire for a yardstick by which to judge the suitability of your product for food purposes. However, no tolerances for poisonous ingredients in foods have been promulgated as yet under the authority provided in Section 406 of the Federal Food, Drug, and Cosmetic Act, \* \* \*. This section of the Act gives the Secretary authority to set up such tolerances only when poisonous or deleterious substances are required in the production of foods or cannot be avoided by good manufacturing practice. In all other instances a strict construction of Section 402 (a) (2) would make any amount of a poisonous or deleterious substance 'unsafe'. We

are of the opinion that it is entirely possible to practically eliminate these two impurities from citric acid and citrates. Therefore, it does not appear that any regulation fixing a tolerance need be promulgated.

"It is of interest to note that the official methods for the determination of lead adopted by the Association of Official Agricultural Chemists use comparatively large quantities of citric acid or citrates as a reagent. These methods were developed for the purpose of measuring accurately the very small quantities of lead sometimes found in food, and in attaining this accuracy it is, of course, essential that the reagents be as free as possible from this impurity. It is now possible to obtain citric acid and citrates for this purpose in which the amounts of lead and arsenic are practically nil."

#### DRUG CONTAINERS, LABELING

Carton for individual tube held to be immediate container as used in Section 201(k) and required to bear labeling same as carton in which dozen such tubes are packed.

TC-45—February 12, 1940

Correspondent packages ointments in tubes for use by physicians for dispensing purposes. The tubes bear a detachable label and are packed in unlabeled cartons bearing a panel on which the physician can write directions. These are packaged twelve in a box bearing a label identical to the one on the tube. Is it necessary to label the individual cartons?

"Section 201(k) of the Federal Food, Drug, and Cosmetic Act defines the term 'label' as a display of written, printed, or graphic matter upon the immediate contain-

er of any article, and further provides that the information required by the Act to appear on the label must also appear on the outside container or wrapper, if any there be, of the retail package. While Section 201 (1) excludes package liners from the meaning of the term 'immediate container', we cannot regard the use of individual cartons as package liners.

"It is our opinion that both sizes of cartons used by you will be required to comply in all respect with the provisions of the Act."

#### WORDING FOR INGREDIENT STATEMENT WHEN PRODUCT CONTAINS PREPARATION OF CRUDE DRUG NOT OFFICIALLY DESCRIBED

When a generally recognized or officially described preparation of a drug such as fluid extract of gentian, extract of aloe, tincture of arnica, or oleoresin of ginger is used as an ingredient, it should be listed by such specific name. Where medicines are prepared from crude drugs by procedures which do not produce any generally recognized or standardized preparations of these crude drug ingredients, if the nature of the product is such that there can be no misunderstanding with regard to fact that the crude drugs are not present as such and if the active principles of the drugs are contained in the finished preparation, the Administration has not objected to statement that the preparation is "made from" the crude drugs listed on the label.

TC-46—February 12, 1940

Correspondent inquires as to whether or not the listing of crude drugs, such as white pine bark and wild cherry bark, as ingredi-

ents of preparations containing material extracted from them and not the crude drugs themselves will meet the requirements of the law.



"The Act requires that the labels of drugs bear lists of their active ingredients in terms of their common names. When a generally recognized or officially described preparation of a drug such as fluid extract of gentian, extract of aloe, tincture of arnica, oleoresin of ginger is used as an ingredient, we think it should be listed by such specific name. It is recognized, however, that in many instances manufacturers prepare their medicines from crude drugs by procedures

which do not produce any generally recognized or standardized preparations of these crude drug ingredients. In such cases, if the nature of the product is such that there can be no misunderstanding with regard to the fact that the crude drugs are not present as such and if the active principles of the drugs are contained in the finished preparation, the Administration has not objected to the statement that the preparation is 'made from' the crude drugs listed on the label."

### GOOSE LIVER PASTE

Name "Pate de Foie Gras" held inappropriate if product made from livers of normal geese. Name is appropriate only if the goose livers used in preparing the paste are obtained from geese which have been forcibly fed to produce the special type of liver generally understood to be used in this product.

TC-47—February 12, 1940

Comment on drafts of labeling for a goose-liver paste bearing the name "Pate de Foie Gras."

In our opinion, this name is appropriate only if the goose livers used in preparing this paste are obtained from geese which have been forcibly fed to produce the special type of liver generally understood to be used in this product. If in fact this goose liver paste is made from the livers of normal geese, the name 'Pate de Foie Gras' is, in our opinion, inappropriate. A product containing normal goose livers should be designated as 'Goose Liver Paste.' In addition, the label must bear a complete list of the ingredients. A statement such as 'Goose Liver Paste with Truffles, Spices, and Salt' would be satisfactory if it is a

complete list. The mandatory label information, namely, the name of the article, the ingredient list, the quantity of contents statement, and the firm name and address, should appear on the label with the prominence required by Section 403(f) of the Food, Drug, and Cosmetic Act.

"It is our understanding that pate de foie gras or goose-liver paste usually contains an added fat, often lard. If any meat product is actually used in the preparation of this paste, it may be a meat-food product and, as such, subject to the requirements of the Federal Meat Inspection Act. If so, inquiry should be made of the Bureau of Animal Industry, which is charged with the enforcement of that Act, submitting the formula for determination of the application of that Act to the product."

### CONFECTIONERY, AMMONIUM CARBONATE

Ammonium carbonate is a drug, and one which will cause candy containing it in a significant amount to be classed as adulterated. Attention directed to Section 402(a)(1).

TC-48—February 12, 1940

Re use of two ounces of "powdered ammonia" to 100 pounds of candy in order to make the candy more porous, the ammonia to be placed in the batch after cooking but while still very hot.

"Ammonium carbonate, which we presume is the form in which you use the ammonia, is a drug and one which will cause candy containing it in a significant amount to be classed as adulterated. In this connection we call your attention to Section 402(a)(1) of the Food, Drug, and Cosmetic Act.

"We are not in a position to state whether

the amount of ammonia remaining in the candy would render it injurious to health, as we do not know what this amount would be or the form in which it would be present. However, if the residue may be injurious, the product would be adulterated. It is the responsibility of food manufacturers to use only wholesome ingredients in the manufacture of food shipped within the jurisdiction of the Act.

"In the event that any harmless residual ammonium compound whatsoever remains in the candy, its presence should be conspicuously declared on the label."



### CHEMICALS IN FOODS

Chemicals may be used in foods if they are incapable of producing harm to the consumers; if they do not conceal inferiority or cause the product to appear better than it really is; and if there is an adequate label declaration of any deviation from the standard or expected identity of the article.

TC-49—February 12, 1940

"I told the visitor that the Administration has no intention of taking the position that chemicals per se must be precluded from food products. It recognizes that modern chemical industry is producing materials that can properly be incorporated in foods and will actually improve them. On the other hand we will oppose with every means at our power the diversion of chemical products to food uses if there is any question of public health or damage to public in-

terest involved. I said that the first criterion, of course, was that the added chemical shall be incapable of producing any harm to the consumer; second, that it shall not conceal any damage nor inferiority, nor cause the product to appear better than it really is—in other words that it shall not debase the article in any respect; and third, that adequate label declaration of any deviation from the standard or expected identity of the article shall be declared \* \* \*."

### GLACIAL ACETIC ACID, DISTILLED VINEGAR

The addition of glacial acetic acid to pure distilled vinegar in any amount would be regarded as constituting adulteration. A declaration of the source of the alcohol used in the manufacture of the article is not required in the case of labels on distilled vinegar.

TC-50—February 12, 1940

"The addition of glacial acetic acid to pure distilled vinegar in any amount would be regarded as constituting adulteration under the \* \* \* Food, Drug, and Cosmetic Act.

"Artificially colored glacial acetic acid is not vinegar of any kind and should not be so labeled. The only appropriate designation for such an article, in our opinion, would be 'Artificially Colored Glacial Acetic Acid'.

"Commercial acetic acid is not a normal or expected ingredient in food products in general, and in those instances where it

might be added without causing an adulteration that cannot be corrected by label declaration, the label of a food to which it is added should bear a plain and conspicuous statement of its presence. Only acetic acid of a degree of purity suitable for such use should be added."

"The Administration does not interpret the requirements of the new act as necessitating a declaration of the source of the alcohol used in the manufacture of the article in the case of labels on distilled vinegar."

### USE OF WORD "PURE" ON FOOD LABELS

"Pure" has several different connotations, which would make a restricted specific definition rather difficult to formulate. Whether the word may be used must be governed by the fact as to whether its use violates that section of the Act which declares that food shall not be labeled in any manner which is false or misleading.

TC-51—February 12, 1940

"The somewhat overworked word 'pure' unquestionably has several different connotations, which would make a restricted specific definition rather difficult to formulate. For example, the word 'pure' on a food product might be interpreted by a consumer as assurance that the article is free from impurities such as deleterious ingredients or ingredients unfit for food for other reasons and, on the other hand, might be interpreted in the sense it is often used

as implying the article conforms to some standard of identity. Since the law contemplates that foods be free from unwholesome or deleterious impurities and that foods for which standards have been promulgated conform to those standards, the word 'pure' is unnecessary in labeling and perhaps the simplest thing is not to be concerned about defining it but avoid its use on labeling where any question as to its interpretation exists."

"\* \* \* Whether or not the word may be



used must be governed by the fact as to whether or not its use violates that section of the Act which declares food shall not be labeled in any manner which is false or misleading. Obviously, the use of the word 'pure' on a single food product which is in

fact pure and which complies in all other respects with the Act would not be false or misleading. The use of the word 'pure' on a combination of food products, such as horseradish and beets, would be certainly inappropriate \* \* \*."

### QUANTITY OF CONTENTS STATEMENT BLOWN IN BOTTLE

To insure meeting requirement of Section 403(f), it is suggested that the quantity of contents statement be prominently set forth on label itself, unless the blown-in-the-bottle statement is unquestionably prominent.

TC-52—February 12, 1940

Under the old Food and Drugs Act there has been a requirement since 1913 that food in package form bear a plain and conspicuous statement of the quantity of contents. We have never looked with favor upon blown-in-the-bottle net contents statements under the old law because they are so apt not to be conspicuous. We are inclined to take the same position under the new act,

which requires the quantity of contents statement to be set forth with the degree of prominence set forth in Section 403(f). In order to insure meeting this requirement, it would be our suggestion that the quantity of contents statement be prominently set forth on the label itself, unless the blown-in-the-bottle statement is so large and so centred on the display face of the package as to be unquestionably prominent.

### VINEGAR

Administration assumed that statement "Diluted (Reduced) to Legal Strength" meant reduced to four per cent acidity, the minimum strength recognized in advisory definition and standard for vinegar under Food and Drugs Act. Statement held to be misleading, and presence of water should be made known under Section 403 (i)(2). Statement might read "Reduced with water to 40 grain strength," etc.

There is no product which could be properly labeled as "compound distilled vinegar" unless it were a mixture of two different lots of distilled vinegar.

TC-53—February 12, 1940

"Three of the labels you submit bear the statement 'Diluted (Reduced) to Legal Strength,' by which we assume you mean that they are reduced to four per cent acidity, the minimum strength recognized in the advisory definition and standard for vinegar under the \* \* \* Food and Drugs Act. The label statement is, therefore, misleading in our opinion. Since in diluting the vinegar water is, of course, added, its presence should be made known on the label in the light of the requirements of Section 403(i)(2). The statement might read 'Reduced with water to 40 grain strength' or 'Diluted with water to 4 per cent acetic acid strength'

or some equivalent expression which clearly shows the addition of water. It should not be referred to as 'legal strength' since there is no legal standard for vinegar under the \* \* \* new Act."

"There is no product which could be properly labeled as 'compound distilled vinegar' unless it were a mixture of two different lots of distilled vinegar. If, on the other hand, your vinegar is a mixture of distilled vinegar and some other kind of vinegar, the name of both vinegars should be set forth on the label. If the vinegar has been reduced to a lower grainage or percentage of acid than the original, that fact should be set forth on the label. \* \* \*"

### DANGEROUS DRUGS—RETAIL PHARMACISTS

The Administration will not undertake the general policing of the retail distribution of drugs. Attention is directed to Section 301(c), whereby the retailer assumes a direct responsibility when distributing drugs over the counter, and to Section 301(k). It is the purpose of the Administration to exercise any authority contained in the Act to insure that dangerous drugs should not be indiscriminately merchandised.



TC-54 [See TC-165, TC-326, TC-361]

February 12, 1940

"The Administration will not undertake the general policing of the retail distribution of drugs. This is a duty imposed upon state and local officials. The Administration, however, will not hesitate to make use of the authority granted it under the provisions of the Federal Act when necessary to protect public health."

"A careful reading of the Act and the regulations for its enforcement will show that certain restrictions are placed upon the sale of drugs which may be dangerous to health when consumed indiscriminately; \* \* \* Manufacturers, in general, are adopting labelings for drug products bearing statements warning against the indiscriminate distribution and consumption of drugs such as those to which you refer.

"Under 'Prohibited Acts,' page 3 of the Act, you will note particularly paragraph (c), which makes it unlawful to offer for delivery, for pay or otherwise, any drug that is adulterated or misbranded after its receipt in interstate commerce. The retailer, therefore, assumes a direct responsibility when distributing drugs over the counter. Aside from this legal responsibility, no retailer with an appreciation of responsibility by reason of his relationship to the public, and the confidence that consumers will

place in his advice, may ignore the warning placed upon the label of a dangerous drug intended to restrict its distribution indiscriminately. The manufacturer's efforts to prevent the distribution of drugs to the laity will avail nothing if the retailer does not cooperate in the refusal to sell such dangerous drugs.

"In our opinion, the refilling of prescriptions for such potent drugs should be authorized by the physician. The patient requiring the administration of such potent drugs should be under the continuous care and supervision of a physician.

"\* \* \* Retail pharmacies should not violate Section 301(k) of the statute, which prohibits the 'alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded'.

"It is the purpose of the Food and Drug Administration to exercise any authority contained in the Federal Food, Drug, and Cosmetic Act to insure that those drugs which, because of their extremely dangerous character, should be distributed exclusively under physician's prescriptions are not in fact indiscriminately merchandised."

### REBOTTLING OF BULK DRUGS BY PHARMACISTS— DIRECTIONS FOR USE

Law requires adequate directions for use to appear upon bulk containers unless exempting provisions of regulations are taken advantage of. Where wholesale package contains such directions, it will be necessary for the retail pharmacist to type the directions on each label.

TC-55—February 12, 1940

"It has been the custom for retailers to buy some drugs in bulk and to retail these in bottles filled by themselves from bulk containers. Some manufacturers seem to feel it is unnecessary to put directions for use on bulk containers on the ground that these do not go to consumers. On the other hand, the retailer will not ordinarily know what constitute adequate directions for use. We have uniformly advised manufacturers that the law requires adequate directions

for use to appear upon bulk containers unless advantage is taken of some of the exempting provisions in the regulations. Where the wholesale package does contain such directions, apparently it will be necessary for the retail pharmacist to type the directions on each label unless there is sufficient demand for any particular article to warrant the printing of a supply of labels for it. The alternative appears to be the purchasing of the article in packages suitable for retail distribution."

### "HABIT FORMING" WARNINGS—PRESCRIPTIONS

Act requires Administrator to list derivatives of substances mentioned in Section 502(d) which may be habit forming. All drugs containing the specified substances must carry the "habit-forming" warning. Even drugs dispensed upon prescription must be so labeled unless prescription is marked as non-refillable.



TC-56—February 12, 1940

"Section 502(d) of the Act lists a number of substances which, when marketed as such or when used as ingredients in other preparations, must bear the legend on the label 'Warning: May be habit forming.' \* \* \* The Act requires the Secretary to list derivatives of \* \* \* substances mentioned in

Section 502(d) which may be habit forming. When the Secretary announces his decision in this matter, all drugs containing the specified substances will be required to carry the warning mentioned. Even drugs dispensed upon prescription must be so labeled unless the prescription is marked as non-refillable."

### **TOMATO JUICE ADDED TO STANDARDIZED "CANNED TOMATOES"**

Optional ingredient (a)(3), Section 53.040 (Federal Register of July 18, 1939), in canned tomatoes has been standardized under its common name as "Tomato Juice," and the label declaration "With Added Tomato Juice" may now be substituted for declaration "With Added Strained Tomatoes" as provided for in Section 53.040 of the regulations.

TC-57—February 15, 1940

Correspondent requested advice as to the proper form of labeling when tomato juice is added to canned tomatoes as the packing medium. The specific question raised was:

"Assuming that optional ingredient (a)(3) in Regulation Section 53.040 is the product for which a standard has been prescribed by Regulation Section 53.000 under the common and usual name 'Tomato Juice', does the declaration 'With Added Tomato Juice', comply with the requirements of Section 403(g)(2) when such optional in-

gredient is used in canned tomatoes?"

"It is the Department's conclusion that optional ingredient (a)(3), Section 53.040 (Federal Register of July 18, 1939), in canned tomatoes has now been standardized under its common or usual name as 'Tomato Juice' and therefore the label declaration 'With Added Tomato Juice' may now be substituted for the label declaration 'With Added Strained Tomatoes' as provided for in section 53.040 of the regulations. Consequently the question you raised is answered in the affirmative."

### **CERTIFIED FOOD COLORS**

Food colors certified under the Food and Drugs Act of 1906 may be considered as being certified under present Act.

TC-58—February 15, 1940

Correspondent asks whether food colors certified under the Food and Drugs Act of 1906 may be used after January 1, 1940.

"We have taken the position that food

colors certified under the Food and Drugs Act of 1906 may be considered as being certified also under the Federal Food, Drug, and Cosmetic Act and therefore may be used after January 1, 1940."

### **POWDER CONTAINERS—DECEPTIVE PACKAGES**

Administration not disposed to object to moderate headspace in powder container to accommodate thin powder puff.

TC-59—February 15, 1940

"The visitors brought a series of different sized powder puffs with them, together with many containers of improved design. \* \* \* Inspection revealed that they had eliminated the objectionable features of the container itself with the exception that the space provided for the puff in the cover of the container was excessive in most instances. The gentlemen argued that the users of these small face powder containers usually wished to insert a powder puff, and that sufficient space should properly be left in the lid to accommodate the puff. \* \* \* The Food and

Drug Administration is not disposed at the present time to insist that such space must be absolutely eliminated. Certainly, however, it would expect that a rule of reason should be applied in that if space is left for the accommodation of a powder puff, it should be moderate and sufficient only to accommodate a thin puff. In other words, any tolerance that might for the time being be admitted as permissible should not be considered a justification for the conclusion that an unreasonably large space in the lid is permissible."



## LABELING STATEMENTS ON COSMETICS IN VANITY CASES, PERFUME BOTTLES, ETC.

Where no printing appears on package except on bottom, a manufacturer may use two labels, one of which would furnish the required information at time of purchase and the other at the time of use. The label which furnishes the information at the time of purchase may be of a type that may be detached; the other must be firmly attached but may be on bottom if likely to be seen.

Under circumstances, if required information is stated conspicuously on a tag and permanently affixed to a label on the bottom of the bottle, labeling requirements of Act will have been met.

TC-60—February 15, 1940

Correspondent's inquiry deals with vanity cases, compacts, and articles which may approach the status of jewelry.

"\* \* \* If products of this sort contain any cosmetic, they should comply fully with the requirements of the statute. \* \* \* The label information required by the act must appear under 'customary conditions of purchase and use.' One label may satisfy these two requirements if it is securely fastened to the main, or display, panel of the container or is a part of the main panel of the container. In those instances where no printing whatsoever appears upon the package except upon the bottom, a manufacturer may wish to satisfy these two provisions of the statute by the use of two separate labels, one of which would furnish the information at the time of purchase and the other at the time of use. If a manufacturer under these circumstances elects to use these two labels, it is our opinion that the label which furnishes the information at the time of purchase may be of a type

that may be detached. The other label, however, which is to furnish the required information at the time of use, must be firmly attached to the container but may be on the bottom if it is likely to be seen in such position under the conditions of customary use. Neither of the two labels alone could be considered as fulfilling the provisions of the statute, but when used together they would appear satisfactory."

Would requirements of statute be met if information required is placed on a tag label to be affixed to the neck of a perfume bottle?

"You point out that the decorative bottle bears no labeling whatsoever and state that it is your purpose to place the required information not only upon the tag but also upon the bottom of the bottle. Under the circumstances, it is our opinion that if the required information is stated conspicuously on the tag and permanently affixed to a label on the bottom of the bottle, the labeling requirements of the statute will have been met."

## SUNBURN PREPARATIONS—SUN TAN

Articles which refer to sunburn or any other disease condition are drugs under Section 201(g), but articles which are represented exclusively for production of an even tan will be regarded as cosmetics under Section 201(i).

TC-61—February 15, 1940

Correspondent requests a statement as to the classification of sunburn preventive preparations under the Food, Drug, and Cosmetic Act.

"The question is not one that can be answered in an unqualified way. The term 'drug' as defined in Section 201(g) is broad enough, in our opinion, to include many products offered for the treatment or prevention of sunburn. The definition of 'cosmetic' in Section 201(i) will likewise encompass some products of this description.

"There are on the market a number of preparations offered for the purpose of acquiring an even tan without burning the skin. They depend upon their property of

screening out rays capable of burning. We are inclined to view products of this description, in which the label claims do not go beyond a prophecy that the products will aid in acquiring an even tan, as cosmetics. Quite obviously, however, the inclusion on the labels of claims suggesting that the products are preventives of or treatments for sunburn may easily throw them into the drug category also, in which case the requirements of the drug sections as well as the cosmetic sections will apply. In determining in which category an article falls, the facts in each particular case must be considered."

"\* \* \* Based upon our present information, we have taken the position that articles



which refer to sunburn or any other disease condition are drugs within the meaning of the statute, but \* \* \* articles which are

represented exclusively for the production of an even tan will be regarded as cosmetics."

### SHORTENINGS—LABEL DECLARATION OF INGREDIENTS

Held, under circumstances presented, that labels such as "made exclusively from Hardened Vegetable Oils," etc., may be considered as satisfactorily meeting the branding requirements of Section 403(i)(2) with respect to listing ingredients of certain shortenings.

TC-62—February 15, 1940

(Letter dated April 12, 1939, signed by Acting Secretary of Agriculture).

"On March 24, 1939, your committee presented a petition for the issuance of a regulation under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act exempting shortenings of the type manufactured by the Institute of Shortening Manufacturers, Inc. from the requirement that the names of the individual animal, vegetable, and marine animal oils and fats entering into the composition of these products be declared upon the labels. You were accorded a hearing on March 29, 1939.

"At this hearing your committee discussed orally and elaborated upon the statements made in the petition which accompanied your letter of March 24, 1939. This petition was supplemented also by a further memorandum submitted by Mr. James G. Parry of your committee on March 30, 1939. It is noted that your products fall into three general types: (1) vegetable shortenings composed wholly of mixtures of edible vegetable oils, which have been subjected to a chemical hardening process known as hydrogenation; (2) mixtures of vegetable oils with or without varying proportions of hardened vegetable oils and with edible animal fats; and (3) hydrogenated mixtures of vegetable oils and marine animal oils. The products under group 2 are in general manufactured under inspection by the Bureau of Animal Industry. The products included in class 1 are labeled 'Vegetable Shortening' or 'Made exclusively from Vegetable Oils'; those in class 3 as 'Made from Marine Oils and Vegetable Oils.' Since, according to our understanding, all the ingredients in types 1 and 3 are subjected to hydrogenation which has the effect of changing the identity of the ingredients, it is the present conclusion of the Department that labels such as 'Made exclusively from Hardened

Vegetable Oils' or 'Made exclusively from Hardened Mixtures of Marine Animal Oils and Vegetable Oils' may be considered as satisfactorily meeting the branding requirements of Section 403(i)(2) of the Act. It is our understanding that the industry is entirely willing to employ this type of branding. Under these circumstances an exempting regulation with respect to these classes of products need not be considered.

"The same reasoning applies to products in class 2 where the entire mixture has been subjected to a hydrogenation process. The Department has reached the conclusion that where such mixtures contain animal fats or vegetable oils which have not had their identity changed by hydrogenation, there is no justification for exempting the products from the requirement that the specific names of these unaltered animal fats or vegetable oils be declared on the labeling.

"In advising you that the vegetable shortenings and the vegetable and marine animal oil shortenings, and those vegetable and animal oil shortenings which have been subjected to the hardening process may be labeled as 'Made from Hardened Vegetable Oils' or 'Made from Hardened Mixtures of Marine Animal Oils and Vegetable Oils,' or 'Made from Hardened Mixtures of Animal Oils and Vegetable Oils' as the case may be, we are discussing exclusively the fats and oils used. Should any non-fat constituents be incorporated, their declaration may be necessary. In addition, the articles should comply with all the other provisions of the statute. Should it later develop that the form of labeling discussed herein either results in deceiving the public or in withholding any substantial information of the kind guaranteed to the consumer by Section 403(i)(2) of the Food, Drug, and Cosmetic Act, the Department reserves the right, on appropriate notice to the industry, to modify this opinion."



## CHEWING GUM—LABEL DECLARATION OF INGREDIENTS

A satisfactory compliance with Section 403(i) will be made in case of ordinary masticatory ingredients of chewing gum if labeled as "masticatory substance" of "gum base." Hydrogenated cottonseed and peanut oils may be declared as "hardened vegetable oils." Other ingredients should be declared by their specific names.

TC-63—[See TC-65]—February 15, 1940

(Letter dated April 29, 1939, signed by Acting Secretary of Agriculture).

"On March 3, 1939, your committee presented a petition for the issuance of a regulation under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act exempting chewing gum from the requirement that the names of the individual ingredients entering into the composition of the product be declared upon the label. You were accorded an opportunity to present your views orally on March 29, 1939, and subsequently supplemented your verbal statements with written memoranda.

"It is noted that some 50 different ingredients are employed at one time or another in the manufacture of chewing gum and that the product consists broadly of:

"(1) A chewing gum base which may contain 12 or more separate ingredients, all of which are covered in the act by the general descriptive name 'masticatory substance' (Section 402(d)). These substances consist of various gums, guttas, and waxes.

"(2) Modifying agents, present in small amounts and varying from 3 to 12 in any one gum, a typical chewing gum containing about 5 modifying agents. Among such agents are mentioned condensed milk, hydrogenated cottonseed oil, peanut oil, olive oil, glycerine, gum arabic, gelatine, cocoa butter and casein.

"(3) Other ingredients. These are mainly carbohydrates and represent approximately 75 per cent of the total weight of the gum, together with flavors and colors.

"Typical formulas submitted indicated that an average chewing gum contains about 25 ingredients, of which 12 fall into the first class, 5 into the second, and 8 into the third. According to the information supplied, a mixture of the various chewing base ingredients is ordinarily impossible either of qualitative or quantitative analysis. The identity of the ingredients is destroyed by the manufacturing process.

"After full consideration of your arguments, it is the conclusion of the Department that a satisfactory compliance with the branding requirements of Section 403(i) of the act will be made in the case of these ingredients if the label declares them as 'masticatory substance' or 'gum base.' This leaves for specific declaration on an average only approximately 13 ingredients which fall into the general categories of 'modifying agents' or 'other ingredients.' Under decisions already made in other connections, it is the Department's conclusion that hydrogenated cottonseed and peanut oils may properly be declared in such mixtures as 'hardened vegetable oils.' Other ingredients which are present in the finished gum should, to comply with Section 403(i), be declared by their specific names. A typical ingredient statement on chewing gum containing for example 12 masticatory base substances, with condensed milk, hydrogenated cottonseed oil, olive oil, glycerine and gum arabic as modifying agents, and sugar, dextrose, dextrin, starch, maltose, corn sirup, flavor and citric acid as other ingredients would read: 'Ingredients: Gum base, condensed milk, hardened vegetable oil, olive oil, glycerine, gum arabic, sugar, dextrose, dextrin, starch, maltose, corn sirup, flavor and citric acid.' Since the Department is not convinced that it is impracticable to make an ingredient statement in these terms or that such a declaration will be either deceptive or result in unfair competition, the application for an exemption under Section 403(i)(2) of the Act is denied. Labels formulated in accordance with the suggestion made above will be regarded as acceptably meeting the requirements of the statute. Should it later develop that the form of labeling discussed herein either results in deceiving the public or in withholding any substantial information of the kind guaranteed to the consumer by Section 403(i)(2) of the Food, Drug, and Cosmetic Act, the Department reserves the right, on appropriate notice to the industry, to modify this opinion."



### FROZEN DESSERTS—EXEMPTION FROM INGREDIENT STATEMENT

In conformity with Section 902(a)(2), the following frozen desserts are exempted from the requirements of Section 403(i)(2) for two years to permit the formulation of definitions and standards of identity under Section 401: Ice cream, frozen custard, ice milk, milk sherbet, and water ice or ice sherbet.

TC-64—February 15, 1940

(Letter dated May 4, 1939, signed by Secretary of Agriculture).

"On April 17, 1939, a delegation from your association presented a petition for the issuance of a regulation under the proviso of Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act exempting frozen desserts from the requirement that the names of the individual ingredients entering into their composition be declared upon the labels. The arguments supporting this request which were made orally on that date have now been submitted by you in written form under date of April 27, 1939.

"In the course of the discussion, spokesmen for the industry reiterated the statement previously made to the Department that the industry desires the promulgation of definitions and standards of identity for these products as provided by Section 401 and because of this had previously requested that frozen desserts be designated as having common or usual names and therefore exempted under Section 902(a)(2) of the act from the requirement for ingredient declaration. It was explained by the delegation that application for an exemption under the proviso of Section 403(i)(2) of

the act was made only because of the inability of the Department to give early attention to the promulgation of definitions and standards of identity.

"Since the appearance of your group before the Department's representatives, the Food and Drug Administration has given further consideration to the possibility of the early formulation of definitions and standards for frozen desserts. It has been concluded that such standards can be formulated and promulgated within the next two years. It therefore becomes unnecessary to issue a regulation exempting these products under the proviso of Section 403(i)(2) of the Act. In lieu thereof and in conformity with Subsection (a)(2) of Section 902 of the statute, the following frozen desserts, having common or usual names, are hereby designated and exempted from the requirements of clause (2) of Section 403(i) of the Act for a period of two years from the date hereof to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by Section 401 of the Act: Ice cream, frozen custard, ice milk, milk sherbet, and water ice or ice sherbet."

### CHEWING GUM—INGREDIENTS AFFECTING PLASTICITY

Ingredients in gum which affect plasticity may be designated "Plasticizing ingredients," "plasticizers," "softening ingredients," or "softeners."

TC-65 (Modifies TC-63)—  
February 15, 1940

(Letter dated August 23, 1939).

"The Secretary's office has referred to this Administration your letter of August 9 in which you further discuss the labeling of chewing gum under the requirements of the Food, Drug, and Cosmetic Act. Your proposal is that chewing gum be labeled with a statement 'Made of Gum Base, Sugar, Corn Syrup, Flavor, and Modifying Ingredients.'

"You recognize that the proposed labeling is not entirely in accordance with the suggestions incorporated in the Acting Secretary's letter to your Association of April 29, 1939, in that it does not identify the various modifying ingredients but proposes a collective term in lieu of their individual

label declaration. In making this proposal you indicate that in the aggregate the substances included in the term 'modifying ingredients' will not exceed 1½ per cent by weight.

"We fully understand the reluctance of the industry to reveal through label declaration those ingredients which are in the nature of trade secrets arrived at by research and experimentation. This, however, is not alone a sufficient reason for failure to disclose the individual ingredients if such a disclosure is of any moment to the consumer. We are frank to say that we are not impressed with the importance to the consumer of a revelation of such ingredients as condensed milk, hydrogenated cottonseed oil, peanut oil, or olive oil, glycerin, gum arabic, gelatin, cocoa butter and casein, the



principal substances listed by your Association as modifying agents, if they are present in amounts not exceeding in all  $1\frac{1}{2}$  per cent by weight and are used solely for retaining the pliability and chewing quality of the gum and to some extent for controlling the rate of release of flavor.

"It does not seem to us, however, that the term 'modifying ingredients' is a satisfactory descriptive name for ingredients having the properties indicated. Any ingredient added to chewing gum, whether flavor, chewing base or sweetening agent, can be considered a modifying ingredient. It seems to us important that some more descriptive term be employed in place of the expression 'modifying ingredients' if the proposed form of labeling which you have submitted is to be regarded as satisfying in a reasonable way the terms of the Acting Secretary's letter of April 29. It appears to us that the principal effect of the modifying ingredients is upon the plasticity of the product. They are in fact 'plasticizing ingredients' or 'plasticizers' and their designation as such would clearly indicate the purpose

for which they are added. No doubt they may also be correctly designated as 'softeners' or 'softening ingredients.' There may be other equally descriptive names. Since all of these ingredients are foods, the expression 'plasticizers,' 'plasticizing ingredients,' 'softeners' or 'softening ingredients' may be properly qualified if so desired with the word 'edible.' It is our conclusion that a label reading 'Made of Gum Base, Sugar, Corn Syrup, Flavor and Edible Plasticizing (or softening) Ingredients' may, at least for the present, be regarded as meeting the requirements of the statute.

"We must, of course, for reasons I am sure you will appreciate, make the same reservation herein that was made in the Acting Secretary's letter of April 29, 1939, namely, that should it later develop that this form of labeling results in deceiving the public or in withholding substantial information from the consumer of the kind guaranteed by the Act, the Administration may, on appropriate notice to the industry, modify this opinion."

#### NON-ALCOHOLIC CARBONATED BEVERAGES—EXEMPTION FROM INGREDIENT STATEMENT

In conformity with Section 902(a)(2), non-alcoholic carbonated beverages are exempted from the requirements of Section 403(i)(2) for a reasonable period of time to permit the promulgation of definitions and standards of identity therefor under Section 401.

TC-66—February 15, 1940

(Letter dated December 4, 1939, signed by Secretary of Agriculture).

"With your letter of July 26, 1939, you filed a petition for exemption of bottled non-alcoholic carbonated beverages under the proviso in Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act, from the requirement of ingredient labeling. On November 29, 1939, you, with other members of a committee of the American Bottlers of Carbonated Beverages, met with representatives of the Department in the Food and Drug Administration to canvass different phases of the subject.

"I am informed that at the conference there was a rather thorough-going review of the questions raised in your petition; that it is questionable whether the facts submitted are sufficient to justify the promul-

gation of a regulation exempting non-alcoholic carbonated beverages from a label declaration of ingredients, under the authority of the proviso in Section 403(i)(2); but that the Food and Drug Administration has given further consideration to the possibility of the early formulation of definitions and standards for carbonated beverages and has concluded that such standards can be formulated and promulgated within the next two years. Therefore, in conformity with Subsection (a)(2) of Section 902 of the statute, non-alcoholic carbonated beverages are hereby designated and exempted from the requirements of clause 2 of Section 403(i) of the Act for a reasonable period of time to permit the formulation, promulgation and effective application of definitions and standards of identity therefor, as provided by Section 401 of the Act."

#### SALAD DRESSING

Administration unable to conclude that term "salad dressing" is the common or usual name for the limited class of salad dressings for which it was desired to apply the term, and unable, therefore, to exempt "salad dressing" from requirements of Section 403(i)(2) pending promulgation of definition and standard of identity. Simplified ingredient declaration was suggested.



TC-67—February 15, 1940

(Letter dated December 22, 1939, signed by Secretary of Agriculture).

"Pursuant to your request of November 30, 1939, and your subsequent communication of December 6, a hearing was granted on December 15 to you and the group of manufacturers who accompanied you by a committee which I designated for the purpose. I now have before me the report of the committee. I have considered it in connection with the written statement of your case included in your letter of November 30 and in your subsequent communication.

"In brief, your contention is that the name 'salad dressing' is a specific name understood by manufacturers and consumers to represent a food composed essentially of mayonnaise salad dressing diluted with varying amounts of starch solution or with water containing such so-called 'stabilizers' as tapioca flour or gum tragacanth; that this product, 'salad dressing,' should be standardized by the Department as provided in Section 401 of the Food, Drug, and Cosmetic Act; and that pending such standardization such food should be designated as having a common or usual name, 'salad dressing,' and exempted for a reasonable time from the requirements of clause (2) of Section 403(i) of the Act, which calls for a declaration of the ingredients of the food product.

"The Department's letter to you of November 20, 1939, indicated that it was entirely willing to act on the application of the industry and at an opportune time call a hearing, as provided in Section 701(e) of the Food, Drug, and Cosmetic Act, for the purpose of considering the possibility of standardizing your product under Section 401. It was stated, however, that the schedule for standard-making operations was such that it is now impossible to predict when such a hearing may be held. In your subsequent correspondence you recognized the possibility that immediate consideration could not be given to the standardization of this food and requested that an exemption be granted under Section 902(a)(2) until such time as a standard can be set up.

"After full consideration of the report of the committee which held the hearing on December 15, I am unable to conclude that the term 'salad dressing' is the common or usual name for the limited class of salad dressings to which you desire to apply it. I am not persuaded that the consuming public recognizes this name as exclusively applicable to your product. Under these circumstances I am unable to exempt 'salad dressing' from the requirements of clause (2) of Section 403(i) pending the possible formulation, promulgation and effective application of a definition and standard of identity therefor.

"In reaching this conclusion I am not unmindful of the difficulties you will encounter if supplies of labels are kept in stock declaring the name of each vegetable oil and each vinegar used in the brands of the product you manufacture. It is my opinion that, pending the possible promulgation of a definition and standard, the requirements of Section 403(i)(2) will be met if the label of this food declares the constituents in the following form: 'Composed of—Edible vegetable oil, eggs, water, a vinegar, starch, sugar, and spices,' the ingredients being declared in the descending order of their proportion by weight and being altered, of course, to fit the circumstances in each particular case. Another suitable form of declaration would be, 'Composed of Mayonnaise Dressing and boiled starch solution' or 'Composed of Mayonnaise Dressing, water, and starch,' provided these statements represent the ingredients in their decreasing proportions. There is, of course, no objection to the statement on the label of additional facts showing the percentage of oil, water, and other ingredients, if a manufacturer elects to do so to facilitate intelligent consumer selection.

"It is my opinion that the use of one of these forms of declaration will eliminate the need for numerous new labels, on which your petition was in part based; it will protect the interest of the consuming public and impose no particular hardship upon the industry."

#### DECLARATION OF PRESERVATIVE IN ICE CREAM

Section 403(k) requires that the label of a food containing any chemical preservative must state that fact, irrespective of whether the food, such as ice cream, is in package form.

TC-68—February 19, 1940

Correspondent advises that in the making of fruit ice cream the preservative in the

fruit flavor (presumably referring to sodium benzoate) would be cut from 1/10 per cent to less than 1/100 per cent of the ice cream



and asks for an interpretation of Section 403(k) of the Act with respect to the necessity for declaration of this small amount of preservative in the ice cream in bulk and in packages.

"Section 403(k) of the law is specific in requiring that if a food contains any chemical preservative it bear labeling stating that fact, irrespective of whether or not it is food in package form. Regulation 403(k),

subparagraph (c), indicates where the statement may be placed. Neither the Act nor the regulations under it mention any percentage below which it is not necessary to declare a preservative. In our opinion, if an amount of sodium benzoate which is detectable by the usual application tests is present, it is required to be properly declared."

### SHERBETS AND ICES—DECLARATION OF ARTIFICIAL COLOR

Sherbets and ices are not covered by the exemption in Section 403(k) that artificial color in ice cream not be declared.

TC-69—February 19, 1940

The gentlemen called to ask whether the proviso of Section 403(k), exempting ice cream from the declaration of artificial color, applies likewise to sherbets and ices. I told them that in our opinion it did not; that the frozen dessert industry made a clearcut distinction between ice cream on the one hand and sherbets and ices on the other; that the proviso in paragraph (k) was inserted on behalf of the dairy industry in order to legitimize butter and cheese manufactured in accordance with previous legislation and containing undeclared color

as allowed by such legislation, and that ice cream was undoubtedly included in the exemption because one of its ingredients may be butter containing undeclared artificial color. Sherbets and ices are not made with butter; they are not considered even by the trade as ice cream and therefore in the opinion of the Administration these products are not exempt from declaration of artificial coloring under the proviso of Section 403(k) but must bear a declaration of such color when present, under Section 403(i)."

### ICE CREAM—PAPER CUP PACKAGES

Side panel shield bearing merely statement "Ice Cream" held not objectionable if all mandatory statements appear on lid. Mandatory label statements may appear either on lid or in side panels, but should not be divided between lid and side panels.

TC-70—February 19, 1940

"\* \* \* As we understand it, you are primarily concerned as to whether, when the mandatory label information is placed on the lid, it then becomes necessary to remove from the sides of the cup itself any label statements which might tend to make a display panel of the side of the cup.

"Your concern, we presume, arises out of opinions we have given that, if any panel of the package is so designed that it might possibly be a display panel, then all of the required information should appear on that display panel.

"In the case of the small (\* \* \*) ice-cream cup all of the required label information appears on the lid, but the two side panels of the carton itself bear the prominent statement '(brand name) Ice Cream' on a shield-like background with no other statements. We are not inclined to object to this container just as it is, even though the prominence given to the name of the

article 'Ice Cream' on these two side panels might conceivably bring those panels into the category of display panels. We think, however, that in the case of this particular package and this particular commodity the labeling on the lid almost invariably comes to the attention of the purchaser just as quickly, if not more so, than does the information on the side panels of the cup.

"In the case of the (\* \* \*) ice-cream carton, the lid is blank, and all of the required information appears on each of the two side panels of the cup. In our opinion, this also is an acceptable manner of labeling, since the absence of any information or design on the lid necessarily forces the attention of the purchaser to the side panels, which thus become in effect display panels.

"In the case of the one-half-pint carton for (\* \* \*) ice cream, part of the mandatory information appears on the lid, namely, the firm name and address, and part on the side panels, namely, the quantity of contents



statement 'One Half Pint.' This, we believe, should be avoided by putting all of the

mandatory label information on the lid if the lid is to be the display panel."

### FROZEN FOODS—LABELING

Administration is not disposed to take exception to such terms as "Frozen Fresh" as applied to packaged frozen foods, provided they are actually fresh when frozen.

TC-71—February 19, 1940

"We have not been disposed to take exception to such terms as 'Frozen Fresh' as

applied to packaged frozen foods, provided they are actually fresh when frozen."

### ICE CREAM—VANILLIN FLAVOR

Ice cream flavored with synthetic vanillin held not strictly vanilla ice cream. Pending establishment of standards, however, no objection would be taken to label designation "Vanilla Ice Cream, Artificially Flavored."

TC-72—February 19, 1940

"Speaking solely from the standpoint of labeling principles applicable to foods in general, it would appear inappropriate to designate ice cream flavored solely with synthetic vanillin as 'Vanilla Ice Cream, Artificially Flavored.' Certainly there is a possible ambiguity about this designation which is not involved in the other name you quote 'Ice Cream Flavored with Vanillin, an Artificial Vanilla Flavor,' and we would therefore be inclined to suggest the second form of labeling. However, in view of the fact that a standard of identity for ice cream

under the new Food, Drug, and Cosmetic Act is slated for early consideration during which the whole question of the 'common or usual name' of ice cream of various types and flavors will no doubt be thoroughly discussed, we do not intend for the time being to institute action against packaged ice cream in interstate commerce flavored with vanillin bearing the labeling 'Vanilla Ice Cream, Artificially Flavored.' It is, of course, definitely required under Section 403(k) of the Act that artificial flavor be declared."

### "FULL STRENGTH" ON FLAVORING EXTRACT LABELS

Since all flavoring extracts must be "full strength," it would be preferable not to use the expression.

TC-73—February 19, 1940

"Since all flavoring extracts and their imitations must be 'full strength' or be classed as adulterated, the use of the expression 'full strength' may be misleading

because it may convey an impression that your flavors are outstanding in this particular. It would be preferable not to use the expression."

### ICE CREAM MIX

Butterfat content of ice cream mix should be such that the finished product will meet butterfat requirements of State laws.

TC-74—February 19, 1940

Correspondent describes a dairy product he proposes to manufacture, indicating that it is similar in analysis to a sweetened condensed whole milk, to be packed in hermetically sealed cans and sold through the grocery trade for the manufacture of an ice cream in refrigerators by the housewife; that the product itself will analyze well above the "United States Standard" for butterfat of sweetened condensed milk, but after dilution with whole milk or water, the

resulting mix will be below the "United States Standard" for ice cream and most of the State standards. Will it be proper to state on the label that upon following directions ice cream could be manufactured from the product in the home, when in reality it would not test up to the Government standards as far as butterfat is concerned?

"The butterfat content of ice cream prescribed under various State laws varies, and for a number of years there has been no



Federal definition and standard of identity for ice cream under the Food and Drugs Act. Certainly, however, it would be misleading, in our opinion, for the labeling \* \* \* to suggest that by following directions ice cream could be manufactured from it in the home if the finished product failed to come up to the butterfat content prescribed by the law of the State in which any particular package is sold. It seems to us that the only practicable thing to do, if you

are going to represent the article as an ice cream mix, is to see that its butterfat content is such that when directions are followed, the butterfat content of the finished product will equal or exceed the butterfat content of that particular State standard having the highest butterfat requirement. The alternative would appear to be the adoption of some labeling which in no way suggests that your product will make an ice cream."

#### VITAMIN CAPSULES—FISH LIVER OILS AND CONCENTRATES

Species of fish from which fish liver oils or concentrates are obtained need not be declared in ingredient statement on label.

TC-75—February 19, 1940

Correspondent has encountered difficulty in obtaining accurate information regarding the exact species of fish represented in fish liver oils and fish liver oil concentrates. Is it necessary to list on the labels of preparations containing such oils or concentrates the species of fish represented, in order to comply with Section 502(e)?

"The Administration will not for the time being object to the use of language

upon labels for products of this kind which will state the fact that the active ingredient consists of fish liver oil or a concentrate of fish liver oils \* \* \*. This is based upon the assumption that the oils or the concentrates in the capsules are intended solely as a source of the contained vitamins and that no representation will be made or implied by the designation of the finished article or otherwise that the material is derived from a particular species of fish."

#### ERGOSTEROL

Activated ergosterol in oil, and unofficial preparations containing activated ergosterol, should be labeled to show specific method of activation.

TC-76—February 19, 1940

Correspondent's inquiry concerns the requirement in the Second Supplement of U. S. Pharmacopoeia XI that the label of activated ergosterol in oil carry a statement of the method of activation of the ergosterol.

"While the Pharmacopoeia contains no statement regarding the basis for this requirement, it is reasonable to assume that the requirement is intended to provide those using or administering activated ergosterol in oil with definite information regarding the particular type of activated ergosterol being used in the event that untoward or unexpected results are obtained. No doubt there are a number of types of statement which would effectively accomplish this end. Since it appears possible that there may be more than one photo-chemical method of activating ergosterol, it is the opinion of this Administration that the statement 'By photo-chemical means' may not provide the

user of an activated ergosterol preparation with definite information regarding the particular type of preparation which he is using. However, we believe that a statement to the effect that the ergosterol is activated by photo-chemical means, supplemented by the name of the particular process employed and the patent number if such exists, would provide sufficiently definite information to meet the Pharmacopoeial requirement under discussion.

"Pharmacopoeial requirements such as the one under discussion are, of course, only directly applicable to official preparations. However, since the Pharmacopoeial Revision Committee has seen fit to require differentiation of activated ergosterol prepared by one process from that prepared by other processes, it appears that it would be in the interest of informative labeling to place such information on the labeling of unofficial preparations containing activated ergosterol as one of their ingredients."



**CONDENSED BUTTERMILK**

Condensed buttermilk, imported in 500-pound barrels for animal feed, is not subject to Import Milk Act but is subject to Federal Food, Drug, and Cosmetic Act.

TC-77—February 19, 1940

Correspondent inquires whether importations of condensed buttermilk manufactured in Canada must be covered by a permit under the Federal Import Milk Act, stating that the article is in semi-solid form, intended for feeding animals, and is packed in fifty-gallon barrels containing 500 pounds net weight.

"At the present time it appears that the terms of the Federal Import Milk Act do not apply to such condensed buttermilk, and, therefore, no permits under that statute will be required as a preliminary to importation.

"However, as the commodity is a food product, importations, as well as interstate shipments within the United States, are

subject to the general terms of the Federal Food, Drug, and Cosmetic Act, which is enforced by this Administration. \* \* \* Stated briefly, the commodity should be true to name, prepared only from sound, wholesome raw material in clean establishments under sanitary precautions, should not be adulterated in any way, and the containers should bear no statements or marks which are false and misleading. Further, the barrels or the containers should bear the mandatory information required under Sec. 403 of the Act, which involves the common name of the article, the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents."

**NEW DRUGS**

New drug section (505) may apply to articles recognized in official compendia as well as to drugs described in "New and Non-Official Remedies."

TC-78—(Undated)

Correspondent advises that the pharmaceutical manufacturing industry is operating on the assumption that a new drug application is not required for a U. S. P., N. F., or H. P. product and asks if this is equally true for "New and Non-Official Remedies."

"As you know, the statute in defining a new drug deals both with the product and its labeling. Ordinarily it may be correctly assumed that products listed in official compendia present no question under the new drug sections of the Act so far as the drug itself is concerned. Ordinarily too, it can be assumed that if the labeling employed in the sale of an official drug was such as to make the product unsafe for use under the conditions prescribed, recommended, or suggested in the labeling, control more ap-

propriately would be undertaken under Section 502(j). We are not prepared, however, to say that in such circumstances both Sections 502(j) and 505 may not be applicable.

"I think this conclusion is justified, particularly in view of the fact that there is nothing to prevent one of the official compendia recognizing a drug which is new as to its composition and which, prior to its listing, has not been placed on the market for general distribution. Certainly, in that event, the fact that it had been recognized in an official compendium would not be regarded as evidence of its exemption from the new drug requirements of the law.

"Of course, the same considerations would apply to drugs described by the Council on Pharmacy and Chemistry in 'New and Non-Official Remedies.'"

**RIBOFLAVIN IN MILK**

Administration is not familiar with any experimental evidence which indicates a measurable degree of destruction of riboflavin when milk is exposed to ultra-violet light to impart antirachitic properties to milk.

TC-79—February 21, 1940

Correspondent's letter contains the following statement and question:

"1. Ultra-violet rays are said to destroy the growth promoting vitamin G. (Meyer Bodansky).

"Milk is an excellent source of vitamin G.

If the above statement is true, the loss by irradiation of milk is greater than its gain. What is the present day consensus of opinion?"

"The term 'vitamin G' is generally applied to the compound which is now known as riboflavin. It has been demonstrated that



pure preparations of riboflavin can be destroyed by exposure to ultra-violet light. The time required for such destruction is a matter of minutes. It has also been shown that concentrates of riboflavin lose their vitamin activity when exposed to intense ultra-violet light for a period of one or two hours. Riboflavin does not occur free in nature but is a component of an enzyme

system which may be more resistant to destruction of ultra-violet rays than the pure compound. We are not familiar with any experimental evidence which indicates a measurable degree of destruction of riboflavin when milk is exposed to ultra-violet light to impart antirachitic properties to milk."

### USE OF TERM "U. S. GRADE A"

The use of the term "U. S. Grade A" to describe food products is misleading because the consuming public recognizes such a commodity as one guaranteed by the Government.

TC-80—February 21, 1940

Correspondent's inquiry relates to the proposed use of the canned food label legend "Grade A The standard of the Agricultural Marketing Service, of the U. S. Dept. of Agriculture for HIGHEST QUALITY FOODS." Correspondent indicates knowledge of the objection which exists to the use of the term "U. S. Grade A," but concludes that since "U. S." is left out of this legend the proposed labeling will be satisfactory.

"The reason for concluding that the labeling 'U. S. Grade A' represented a violation of the Food and Drugs Act was the very definite indication, by various surveys made at different times, that the consuming public recognized the commodity upon which such labeling was employed as one which had been guaranteed by the Government. It is quite natural that such belief would prevail in view of the rather extensive supervisory manufacturing services rendered by different branches of the Government. For instance, three bureaus within this Department are engaged in the maintenance of continuous inspection over the operations of food manufacturing establishments, the output of which is properly labeled in a manner to indicate Government sponsorship of wholesomeness and quality. We cannot

escape the conclusion that the use in labeling of the term 'U. S. Dept. of Agriculture' may indicate to the purchaser that the particular lot of canned goods has been produced under continuous supervision of the Department.

"It is true that the legend which you propose is the truth, but that fact does not guarantee its legality if used on canned foods. The statute prohibits the use of labeling which is false or misleading in any particular. The Supreme Court, in speaking of this particular requirement, has said:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false.'

"If the legend which you propose to use is actually employed and it does deceive and mislead, and our investigations on the basis of similar expressions have established conclusively in our mind that it will, the Food and Drug Administration will have no alternative to the institution of appropriate action whenever interstate shipments occur."

### RAW MATERIALS—SECTION 405

The exemption authorized by Section 405 is not intended to cover the various raw materials used in the manufacture of food products.

TC-81—February 21, 1940

Correspondent asks if the various ingredients used in his plant can be purchased and shipped under code designations, in the belief that an exemption of this nature is authorized by the provisions of Section 405.

"Our familiarity with the legislative history of this particular section justifies us in

concluding that it was not the purpose of Congress to have the exemptions authorized under Section 405 cover the various raw materials used in the manufacture of food products. This section represents a legislative sanction of an administrative practice that prevailed under the old statute, of permitting the segregation in a central estab-



ishment of the output of various branches for labeling and such incidental processing as might be involved in the final preparation of an article for sale to the public. I know personally that it was never intended by it

to authorize an exemption of traffic generally in various types of products used as ingredients in the production of articles subject to the Act."

### ANTHELMINTICS FOR ANIMALS—WARNINGS

The warnings referred to in "TC-14," although intended primarily for human preparations, should be made use of wherever applicable for veterinary products. The warning statements for anthelmintics for animals should also state that the preparation is toxic under certain conditions and should not be administered to sick animals.

TC-82—February 21, 1940

Correspondent's letter concerns warning statements on certain drugs from the standpoint of the Federal Food, Drug, and Cosmetic Act.

"While the warnings to which you refer '(see TC-14)' were intended primarily for human preparations, they should be made use of wherever applicable for veterinary products. \* \* \* Since all known effective anthelmintics are more or less toxic to animals under certain conditions, we are of the

opinion that in addition the warning statements for anthelmintics for animals should include that the preparation is toxic under certain conditions and should not be administered to sick or weak animals. Where a large number of animals are to be dosed with such products, we also believe that the directions should call for the treatment of a few animals at a time to determine any unfavorable reaction before dosing all of the animals."

### DRUGS MANUFACTURED ON PHYSICIAN'S ORDER

A manufacturing order for drugs to be delivered to a physician for ultimate dispensing and not directly to the patient is not subject to Section 503(b)(1) and (2).

TC-83—February 21, 1940

Correspondent's letter transmitted an order from a physician and a formula for a batch of tablets the physician has been using and which he wishes the correspondent's firm to refill for his use. It is the correspondent's opinion that he may fill and deliver this prescription for the doctor without in any way violating the Act as it would be exempt in accordance with Section 503(b)(1) and (2).

"A written prescription such as is con-

templated in Section 503(b) of the Act is given by the physician to his patient with appropriate directions for his own personal consumption after it is filled by the druggist. The formula which you submit with your letter \* \* \* is in fact a manufacturing order for goods to be delivered to the physician for ultimate dispensing and not directly to the patient who is to consume it. It is not, therefore, subject to Section 503(b)(1) and (2) in the opinion of this Administration \* \* \*

### WARNINGS

The suggestions for warnings in "TC-14" may in some instances be inappropriate, unnecessary, or inadequate.

TC-84—February 21, 1940

"With reference to the suggestions for warnings contained in our letter of December 29, 1939, addressed to our field representatives, '(TC-14)' it is realized that

there may be instances in which such warnings are inappropriate or unnecessary. It is also true that there may be instances in which they would be inadequate and more specific warnings would be required."

### WARNINGS

The omission of appropriate warnings is not justified merely because a preparation is intended for the use of physicians.



TC-85—February 21, 1940

"\* \* \* We do not think, however, that merely because a preparation is intended for the use of physicians the omission of ap-

propriate warnings is justified. Neither the law nor the regulations make provision for such omission on the ground that the article is intended for professional use."

### SAMPLE PACKAGES—PHYSICIANS

Sample packages distributed to physicians are not exempt from mandatory labeling requirements of Act.

Sample packages are subject to the same requirements as commercial size packages.

TC-86—February 21, 1940

Correspondent inquires if there is a different ruling as to the labeling of samples for distribution to physicians.

"There is no exemption under the Federal Food, Drug, and Cosmetic Act as to the

mandatory requirements of this Act in labeling samples distributed to physicians."

"\* \* \* You will note that sample packages are subject to the same requirements as commercial size packages. \* \* \*"

### PROCESS CHEESE

Cheese component should conform to advisory standard for process cheese, pending promulgation of definitions and standards of identity.

TC-87—February 21, 1940

Correspondent requests information as to the present standards for water and butterfat in different varieties of process cheese.

"Under the new Federal Food, Drug, and Cosmetic Act no standards have been promulgated up to this time for cheeses or process cheese. At the present time we are guided in enforcement of the law by the advisory standards for these products adopted under the Food and Drugs Act of 1906, as given in the circular S. R.A., F. D. No. 2. As you will note on page 6 of this publication, process cheese must conform in composition, with respect to fat and moisture content, to cheese of the variety from which

the process cheese purports to have been made. In the case of Cheddar cheese it must have not less than 50 per cent of milk fat in the water-free substance and not more than 40 per cent of moisture or water. In the absence of a standard for pimento process cheese we have interpreted this definition as requiring that the cheese component of the mixture conform to the standard for process Cheddar cheese, although we realize that the mixture of process cheese and pimentos, on the whole, may exceed the 40 per cent moisture requirement because of the high moisture content of the pimentos added. \* \* \*"

### "BUTTER-NUT"

The term "Butter-Nut" on bread is capable of misinterpretation.

TC-88—February 21, 1940

Correspondent inquires as to the propriety of the name "Butter-Nut" on the wrapper for an ordinary white bread. The label also carries the legend "Genuine Butter-Nut Bread," which implies that it is a distinctive type of bread.

"The term 'Butter-Nut' is one readily misinterpreted. To some it may imply a bread where the sole shortening ingredient

is butter, and with an appreciable quantity of nuts or a nut product, or perhaps to some it may mean a bread containing substantial amounts of butternuts. The fact that the term may have been in general use does not authorize its use if it in fact misleads consumers. Continued use of the name on ordinary white bread must be on the sole responsibility of the shipper."

### HONEY BREAD

At least eight per cent of honey should be used in a bread labeled as honey bread. If lesser quantity is used, the honey ingredient should not be featured other than as one of the sweetening ingredients.



TC-89—February 21, 1940

"Under the provisions of the new Food, Drug, and Cosmetic Act, \* \* \* the Department is authorized to promulgate legal standards of identity for food. At some time a standard of identity for honey bread may be established, but in the meantime the general labeling provisions of the new Act

will govern the use of honey in bread.

"Our opinion has not changed that at least eight per cent of honey should be used in a bread labeled as honey bread. The use of a lesser quantity is not prohibited, but in that case, the honey ingredient should not be featured other than as one of the sweetening ingredients."

#### "BUTTER CREAM LOAF"—"CREAM"

The term "Butter Cream Loaf" is unobjectionable if butter and cream are the sole shortening ingredients and no consumer deception results. Synthetic cream made by emulsifying butter with fresh milk is not entitled to the designation "cream."

TC-90—February 21, 1940

Correspondent's first question deals with propriety of the name "Butter Cream Loaf" for a bread which at all times contains substantial amounts of both butter and cream as the sole shortening agents.

"The test of the propriety of such a term is, of course, whether or not it does deceive consumers. If they understand that the words 'Butter' and 'Cream' refer to the shortening, and these are the only shortening agents used, we see no objection to the name."

Correspondent's second inquiry is with respect to the propriety of the name "Cream" in the ingredient statement on the loaf of bread, which contains a so-called "synthetic cream" only which is made by passing a

mixture of pure butter and fresh milk through an emulsifier.

"In this case, our answer must be unqualifiedly in the negative since such a physical mixture of butter and milk is in no sense cream. In our opinion, these two ingredients should be referred to in the ingredient statement as 'Butter' and 'Milk.' If the amount of milk present is less than that which is required in standard milk bread, we believe that in order to avoid giving the impression that the article is in fact a milk bread it would be necessary, in the light of Section 201(n) of the Food, Drug, and Cosmetic Act, to qualify the reference to milk in the ingredient list with a statement that the product is not a milk bread."

#### BAKERY PRODUCTS—BREAD

Water, if in fact removed during the baking process, need not be declared as an ingredient.

The fact that water is used to fabricate the doughs need not be set forth on label of baked goods where the water added is largely, if not entirely, lost in the baking process.

TC-91—February 21, 1940

Inquiry concerns the labeling on importations of Swedish Rye Bread.

"\* \* \* if the water used in manufacturing is removed entirely during the baking process, then this ingredient need not be declared on the label. On the other hand, if some of the added water remains in the finished bread, then water should be declared as one of the ingredients. It must be borne in mind that the other constituents, viz. whole rye or rye meal, salt, and yeast all contain some native moisture. It is not safe to assume that because the finished bread is dry to the senses it does not contain any added water, and this fact can be established accurately only through analysis.

The manufacturer can determine this by learning the exact amount of moisture contained in the original whole rye or rye meal, salt, and yeast and comparing this with the amount of moisture in the finished bread. If the moisture content of the latter has not been increased, then the added water need not be declared as one of the ingredients."

Correspondent asks whether, in listing ingredients on labels for baked goods, it is necessary to indicate that water is used to fabricate the doughs.

"We are not disposed to insist that this fact be specifically set forth on the label of ordinary baked goods where the water thus added is largely, if not entirely, lost in the baking process."



**"BUTTER FLAVORED"—"BUTTER COOKIES"**

"Butter Flavored" is applicable only if sufficient butter is used to flavor the finished product and the ingredient statement shows that most of the shortening used is other than butter.

No assurance can be given that the term "Butter Cookies," etc., can legally be applied to articles containing other shortening ingredients besides butter.

TC-92—February 21, 1940

"You ask whether you are justified in using the name 'Butter Flavored Cookies' on cookies the shortening ingredient of which contains about six per cent butter. If the amount of butter is sufficient to contribute flavor to the finished product, they may be referred to as 'Butter Flavored Cookies' provided the ingredient list sets forth the fact that most of the shortening is other than butter. This could be accomplished by some such statement as 'Shortening (6 per cent Butter, 94 per cent Other Shortening).'

"In regard to your inquiry as to 'what percentage of the total shortening content would have to be butter before we could call an item a 'Butter Cracker', we can only refer you to our repeatedly reiterated comment that there is evidence that consumers in many instances interpret the unqualified word 'butter', as applied to cookies, wafers, crackers, etc., to mean that the shortening ingredient is butter only, and we can give no assurance that the terms 'Butter Cookies', 'Butter Wafers' and 'Butter Crackers' can legally be applied to articles containing other shortening ingredients besides butter."

**VITAMINS**

Information is given concerning the proper method of expressing the vitamin content of food products.

TC-93—February 21, 1940

Correspondent requests information concerning the proper method of expressing vitamin content of food products.

"When the vitamin content of a food product is indicated on the label in terms of units, it should be stated what particular units are referred to. At the present time vitamin A and D potency appears to be expressed universally either in U. S. P. or International units. These units have the same value and may be used interchangeably. We believe that vitamin B<sub>1</sub> potency should be expressed in International units. The Chairman of the U. S. Pharmacopoeia Revision Committee has recently announced the adoption of a U. S. P. standard for vita-

min B<sub>1</sub>, and the U. S. P. unit is now defined in the same manner as the International unit; that is, the biological activity of three micrograms of crystalline vitamin B<sub>1</sub> hydrochloride. There will, therefore, be no objection to expressing vitamin B<sub>1</sub> content in U. S. P. units in the near future. Vitamin G potency has been expressed almost universally in terms of Sherman-Bourquin units. Since it has been shown that the Sherman-Bourquin method determines riboflavin, we believe it preferable to refer to that compound and express potency in terms of weight of riboflavin in a given quantity of material. There are at present no generally accepted units for expressing vitamin E potency."

**BAKERY PRODUCTS—SHORTENING AND LEAVENING INGREDIENTS—YEAST NUTRIENTS**

Where particular shortening or leavening ingredients cannot always be predicted in advance, they may be declared as "shortening" or "leavening" in lieu of naming each specific substance.

In the case of those breads which require the listing of ingredients, the expression "yeast nutrient" or "dough nutrient" may be used when true to fact.

TC-94—February 21, 1940

"In the case of shortening and leavening, we have taken the position that where particular shortening or leavening ingredients that may be used at any given time by a manufacturer cannot always be predicted in advance, we would not object to declar-

ing such ingredients by the term 'shortening' or 'leavening,' as the case may be, in lieu of naming each specific substance. This is on the understanding that if it develops that the practice results in denying the consumer the information which the provisions of the law guarantee, it will be necessary,



after due notice, to abrogate this permission."

Correspondent inquires whether a product composed of condensed cultured buttermilk, common salt, ammonium chloride, and potassium bromate may be designated on the label of bread as "yeast nutrient."

"Undoubtedly you know that white bread, whole wheat bread, raisin bread and milk bread are exempt from the requirement of Section 403(i)(2) that ingredients be listed, pending the formulation of standards for these products under the authority of

Section 401. These standards are now under consideration. In the case of those breads which do require the listing of ingredients, the expression 'yeast nutrient' or 'dough conditioner' may be used on the label when such expressions are true to fact. If the ingredients belong under both classifications—so-called yeast nutrients and dough conditioners—both expressions may appear on the label, or a declaration of the actual ingredients, which would be preferable."

### NEW DRUGS

Section 505 does not provide for the approval of applications. They become effective through absence of an order of refusal.

TC-95—February 21, 1940

"In the first place, a manufacturer does not apply for permission to sell a new drug. He places before the Secretary an application with respect to a new drug, and this application must become effective before the drug may be legally shipped in interstate commerce. An application becomes effective if no order issues refusing to permit it to become effective and our communications to manufacturers who have

filed applications with the Secretary clearly announce this fact as follows:

"\* \* \* Consideration of the application has been completed. It has been concluded that no order will issue under section 505 (d) of the Act to refuse to permit the application to become effective \* \* \*."

"The Act does not provide for approval of applications, but authorizes the Secretary to reach a conclusion with respect to the safety of the article."

### LABELING OF ICE CREAM CARTON

Advice given as to method of labeling particular ice cream carton designed to hold one quart.

TC-96—February 21, 1940

Visitor at interview requested that he be advised by letter in regard to the labeling of one particular ice cream carton designed to hold one quart.

"This carton has the general shape of a butter carton, except that instead of having four rectangular panels of the same size, the top and bottom panels are a little wider than the side panels. The carton when filled with ice cream is to be opened by pulling up the flap which extends part way down the side panel, this flap being an extension of the cardboard forming the top of the container. The carton submitted bears no wording except 'Ice Cream,' which appears in white on a band of blue on each of the four rectangular panels. All of the carton has a waxed surface except the flap and you requested to be advised whether or not it would be permissible to place the mandatory label information on this type of carton in a conspicuous fashion on the flap, since this is the only place which can be readily printed or rubber-stamped in view of the waxy coating on

the remainder of the carton. You stated that this will enable the ice cream seller to use this one stock carton for various flavors, stamping the name of the flavor, the net volume statement, and the firm name and address on this flap.

"As we advised you at the time of your visit, the shape of this carton is such and the design on the top of the carton is such as, in our opinion, to inevitably focus the attention of the purchaser on the words 'Ice Cream' appearing on the top of the carton and in so doing will likewise draw the attention of the purchaser to any prominent statement which may be imprinted or stamped on the flap on the vertical front of the package. We will, therefore, have no objection to such a position for the mandatory information on this particular carton, but as we pointed out to you, this is not to be interpreted as sanctioning the use of the vertical side of the carton in every case for the mandatory label information. As we pointed out, the tops of some cartons \* \* \* are so designed as to concentrate the attention of the purchaser on



the top of the carton to the extent that any printed statement appearing on the side of the carton might readily be overlooked. We think that as a further means of securing a literal compliance with the require-

ments of section 403(f), it would be advisable to omit the name 'Ice Cream' from the bottom panel and the side panel opposite to the flap."

### TEA BAGS

Tea bags in retail unit carton need not be individually labeled if carton bears mandatory statements.

TC-97—February 21, 1940

Correspondent requests information concerning labeling of tea bags under the Food, Drug, and Cosmetic Act.

"As we understand it, the tea is packed in small individual bags, several of these bags of tea being enclosed in a package suitable for use as a unit of sale to consumers. Since the bags do not appear to be a unit of sale but merely constitute convenient sub-divisions of the retail package, it is our opinion that the provisions of Section 403 of the Act will be met if the man-

datory label information required by this section is prominently set forth on the outside of the carton without being repeated upon each bag. The statement of net weight on the carton should be the total net weight of tea in the carton, exclusive of the tare weight of the bags themselves. Of course, there would be no objection to stating in addition the number of tea bags in the carton. We believe it desirable if not essential that a statement of the number of tea bags also be set forth on the carton label."

### TINCTURE OF IODINE U.S.P.

Suggested directions for use of Tincture of Iodine in the interest of safety are given.

TC-98—February 21, 1940

Correspondent requests comment on a proposed label for Tincture of Iodine U.S.P.

"\* \* \* We suggest that the label bear directions to apply lightly, not more than once a day and not to use with a bandage. If the article is to be used repeatedly, direction to dilute with two or three vol-

umes of water before use would be in the interest of safety. If desired, such warnings may appear in the place of the declaration of alcohol, which is not required under the Federal Act. (This declaration may, however, be required by some state acts. We have no specific information in this connection.)"

### BUTTER—"FRESH"

The term "fresh" is generally understood to indicate an article of recent origin, and would be inappropriate on cold storage butter.

TC-99—February 21, 1940

"We note the inclusion on this wrapper of the unusual word 'fresh.' Since the word 'fresh' is generally understood by a consumer to indicate an article of recent origin, we would regard the use of this word as appropriate only if the butter had been

recently churned. You will appreciate, I am sure, that this term is hardly applicable to butter which has been kept for a length of time, such as in the usual commercial practice of storing butter in cold storage warehouses until such time as it is placed on the market."

### TONGUE DEPRESSORS—WOODEN APPLICATORS

Tongue depressors and applicators are devices under Section 201(h).

TC-100—February 21, 1940

Correspondent inquires whether wooden tongue depressors and wooden applicators will be subject to the provisions of the Federal Food, Drug, and Cosmetic Act.

"We \* \* \* direct your attention to the definition of the term 'device' which appears in Section 201(h). It is our opinion that tongue depressors and applicators are devices as this term is defined in the Act. The



provisions of the Act relating to devices will be found in Chapter V, and as far as they relate to this type of product are comparatively simple. Section 502(b) will require the label to bear an accurate statement of the quantity of contents and the name and address of the manufacturer, packer, or distributor. In order to comply with the provisions of Section 502(c) this

information should appear on the main display panel.

"Unless the use of such devices is generally known to the consumer, Section 502 (f) will require the labeling to bear adequate directions for use. In addition, the method of packaging should not be deceptive in any manner in order to comply with Section 502(i)."

### SHORTENINGS—LECITHIN

Lecithin is not a normal ingredient of shortening and should be declared as an ingredient.

TC-101—February 29, 1940

Correspondent's inquiry concerns the use of lecithin in shortenings.

"We have always regarded lecithin as an abnormal ingredient, that is, not an ingredient customarily expected by the consum-

ing public in shortening or associated with shortening. Consequently, as we have recently advised other inquirers, the presence of lecithin should be declared among the ingredients when introduced into a food in a shortening or along with a shortening."

### HAIR DYES—HYDROGEN PEROXIDE—COAL-TAR COLORS

The caution statement prescribed by Section 601(a) should appear on the bottle of hydrogen peroxide, as well as on the bottle containing a coal-tar component, if both are sold as a unit.

TC-102—February 29, 1940

Correspondent wishes to know whether the caution statement prescribed in Section 601(a) should be affixed to each of the two units comprising a package of coal-tar hair dye (oxidation type), one unit of which carries all of the active ingredients, the other containing the oxidizing agent which is usually hydrogen peroxide.

"It is our judgment that under the definition of 'label' set forth in paragraph (k) of Section 201, the Administration does not have the authority to exempt from the use of this precautionary label those packages which contain products other than the coal-

tar dyes, such for instance, as hydrogen peroxide. Because of the importance of the precautionary statement being read by the persons who will use or apply this dye, I am inclined to think that authority for such exemption would not be exercised even though it existed. The necessity for avoidance of the consequences which might otherwise occur dictates, it seems to me, the necessity for this decision. Furthermore, in our examination thus far of such products we have found that the oxidizing agent, hydrogen peroxide, is itself capable of producing serious irritation of the eyes."

### HAIR DYES—COAL-TAR COLORS

Hair dyes containing harmless coal-tar colors need not bear the caution statement required by Section 601(a) even though the colors are not certified.

TC-103—February 29, 1940

"It is our opinion that if a hair dye contains harmless coal-tar colors, it is not necessary that the labeling bear the caution statement required by Section 601(a), even though the coal-tar colors are not certified. At this time we are not in a position to state what colors, other than those which have been announced in the color regulations, are harmless and suitable for use. If a manufacturer elects to delete the caution statement and use colors that are

not certified, he must assume all responsibility should it be found that the colors used may in fact be dangerous. It is needless to say that a manufacturer may avoid the possibility of violating Section 601(a) by resolving all doubts in favor of uncertified colors being harmful and labeling coal-tar hair dyes with the caution legend prescribed in the statute. You will note in this connection that if the colors which you propose to use in your product are in fact harmless and suitable for use, such colors may be



certified after they have been admitted to the list of permitted colors. The way in which such colors may be added to the per-

mitted list is dealt with in the coal-tar color regulations.

### FLAVORS—"TRUE FRUIT"

Flavors made from the oil of orange, lemon, or lime are not "true fruit flavors." However, they are not artificial flavors.

TC-104—February 29, 1940

"Flavors made from the oil of orange, lime, or lemon are not and never have been considered as 'true fruit flavors,' since this term is properly applicable to a flavoring

concentrate prepared from whole fruit or fruit juice. However, flavors made from oils of orange, lime, or lemon are not artificial flavors."

### SUPPORTERS—SUSPENSORY BANDAGES—WRIST BANDS

Athletic supporters, suspensory bandages, elastic and leather wrist bands, and ankle supports are devices under Section 201(h).

TC-105—February 29, 1940

Correspondent asks whether athletic supporters, suspensory bandages, elastic and leather wrist bands, and ankle supports are

subject to the requirements of the Act.

"\* \* \* You will note that these articles are devices as that term is defined in Section 201(h).\* \* \*"

### "VITAMIN F"—UNSATURATED FATTY ACIDS

The term "Vitamin F" is misleading and should not be applied to unsaturated fatty acids essential to nutrition.

TC-106—February 29, 1940

In considering the label for a proprietary product, the opinion was expressed that the statement "Contains a large number of Vitamin F Units." is false and misleading.

"There have been at least three separate proposals to apply the term 'Vitamin F' to wholly unrelated substances, none of which has received important recognition. Investigators in the field of nutrition have established that certain unsaturated fatty acids, principally linoleic and linolenic, are essential in the nutrition of certain species of animals. In some of the earlier reports, some of these investigators suggested that these fatty acids might well be called 'Vita-

min F'. This idea was taken up by certain commercial interests who have developed a rather widespread business in the distribution of refined linseed oil as a source of vitamin F. However, scientists generally do not agree that these unsaturated fatty acids should be called vitamin F, and within the past year or so the American Society of Biological Chemists, the American Institute of Nutrition, and the Association of Official Agricultural Chemists have each approved reports or resolutions to the effect that the unsaturated fatty acids essential to nutrition should not be called vitamin F."

### "ENCAPSULATING" OR "TABLET COMPRESSING" OPERATIONS

"Encapsulating" or "tablet compressing" operations, with no additional operations, do not constitute "manufacture."

TC-107—February 29, 1940

Correspondent requests determination of the status of a person who prepares a drug product and delivers it to another for encapsulating.

"Where two or more parties are responsible for different phases of operations involved in the fabrication of foods, drugs, or cosmetics, it is not an easy matter to determine always what their respective posi-

tions in the light of the law may be as 'manufacturer', 'packer', or 'distributor'. As a rule for our guidance in response to inquiries we have concluded that ordinarily the party who completed the manufacturing operation should be regarded as the manufacturer.

"In the instance which you cite the concern last handling the preparation before it was placed on the market made no contri-



bution apparently to the manufacturing operation except encasing the drug in capsules. In such circumstances I am inclined to believe that this illustration is not covered by the rule to which I have referred. If 'A' manufactures the drug, owns it, and delivers it to 'B' for the sole purpose of packaging, whether in capsules, bottles or otherwise, obviously 'B's' name could appear on the label only as packer, and we will not be disposed to consider the appearance of 'A's' name on the label as manufacturer in conflict with section 502(b)."

"When \* \* \* was at the Administration offices some days ago he inquired as to the status of your firm in connection with the distribution of tablets composed of in-

gredients mixed and assayed by your firm and shipped to a tablet manufacturer merely for the purpose of compressing into tablet form and reshipped to you for assay, packaging, and marketing.

"Under the circumstances outlined, this Administration will regard your firm as the manufacturer. Of course, if the tablet manufacturer adds any ingredients to the mix, or places a coating of its own manufacture on the tablets, or does any act other than merely compressing the material furnished by you into tablet form, we would regard him, not your firm, as the manufacturer. In that case your label should indicate that you are the distributors of the goods."

### "TOMATO JUICE COCKTAIL"—CHILI JUICE

The term "tomato juice cocktail," but not "tomato juice," is appropriate for tomato juice seasoned with green chili juice.

TC-108—February 29, 1940

"A definition and standard of identity effective January 1, 1940, has been promulgated for tomato juice. It is noted that the label reads '\* \* \* A Tomato Juice Seasoned With Green Chili Juice and Salt.' Although salt is recognized in the standard as an optional ingredient, the presence of which need not be declared on the label, there is no provision in the standard for the addi-

tion of chili juice. It follows, therefore, that this product may not be sold under the name 'Tomato Juice.' It is, however, of a composition which in our opinion would class it as a tomato juice cocktail. If, therefore, the word 'cocktail' is added to the words 'A Tomato Juice,' in letters of the same prominence, and an ingredient list follows, we would have no further comment."

### TOOTH BRUSHES—SHAVING BRUSHES

Ordinarily tooth brushes and other comparable types of toilet brushes, such as shaving brushes, are not therapeutic devices. Status of such products, however, is predicated on the representations made for them.

TC-109—February 29, 1940

Correspondent inquires with regard to the status of shaving brushes under the Federal Food, Drug, and Cosmetic Act of 1938.

"There have not as yet been any court decisions which authoritatively fix the limits of products subject to regulation as drugs, devices, or cosmetics. For the time being at least, it is our opinion that articles sold simply as shaving brushes are not subject to regulation under the terms of the Act."

"\* \* \* it is our opinion that ordinarily tooth brushes and other comparable types of toilet brushes are not therapeutic devices within the meaning of the \* \* \* Act."

"We cannot categorically state whether or not a toothbrush would be subject to the requirements of the statute. In answer to

similar inquiries from the trade, we have stated that the status of such products is predicated upon the representations made for them. It is our view that if the products are not medicated, and no representations are made to infer that the articles are intended to cure, mitigate, or in any other way serve in the treatment or prevention of disease, or affect the function or structure of the teeth or gums, the articles would not be classified as devices under the drug section of the Act. Likewise, if the article is sold merely as an adjunct in the cleaning of the teeth, at the present time we are not inclined to consider it under the cosmetic section of the Act."

"It is further our view that utilization of the term 'sterilized' upon these commodities would not of itself classify them as therapeutic devices. \* \* \* If a tooth brush



were represented as useful in causing spongy gums infected with pyorrhea to become firm and healthy, the article could unquestionably be a therapeutic device. If the article were thus to become a therapeutic device, it is our opinion that the appearance of the word 'sterilized' upon the product would mean to the average consumer that it is so manufactured, packaged, and handled as to be sterile when purchased.

"Mr. \* \* \* explained that statutes of New York State and elsewhere require various products made in part from animal bristles to be sterilized against anthrax and

to bear the word 'sterilized'. So far as this Administration is concerned, if the article is sold under representations which do not classify it as a therapeutic device, the appearance of the word 'sterilized' upon the article is a matter over which the statutes enforced by this Administration have no control. If, however, by virtue of representations made concerning the articles they become therapeutic devices, then possibly the word 'sterilized' should be so qualified as to indicate the sterility involved is limited to the organism responsible for anthrax and is not surgically sterile."

### HOT WATER BOTTLE—SYRINGE

A syringe is a device under Section 201(h). The only information required to appear on label of a hot water bottle is the name and address of the manufacturer, packer, or distributor and the number of bottles in the package.

TC-110—February 29, 1940

Correspondent asks whether a rubber water bottle or syringe will be classified as a "device" under the provisions of the Act.

"We \* \* \* direct your attention to the definition of the term 'device' which appears in Section 201(h). It is our opinion that a syringe is a device as this term is used in the Act.

We have had no occasion to secure legal

opinion in regard to the status of hot-water bottles under the Act, and no court decisions have been handed down on this subject. However, we wish to point out that the only information which is required by the Act to appear on the label of a hot-water bottle is the name and address of the manufacturer, packer, or distributor and the number of bottles in the package."

### COMB

A comb labeled "For Dandruff and Scalp Infections" is a device under Section 201(h).

TC-111—February 29, 1940

"The comb is labeled 'For Dandruff and Scalp Infections' and in our opinion is

clearly a device as that term is used in Section 201(h) of the Act; it is therefore subject to the requirements of the Act."

### RAZOR BLADES—MANICURING INSTRUMENTS

Razor blades and manicuring implements, as ordinarily represented, are not devices under Section 201(h).

TC-112—February 29, 1940

Correspondent inquires whether the term "device" as used in Section 201(h) of the Act includes such items as razors and manicuring implements.

"You will note in the study of this definition that devices are subject to the Act only when used in the diagnosis, cure, mit-

igation, treatment, or prevention of disease in man or other animals, or when they are used to affect the structure or any function of the body of man or other animals. Razor blades and manicuring instruments as ordinarily represented are not devices, in our opinion, within the meaning of the Act."

### DEVICES

The Act makes no provision for the submission to the Administration of applications in connection with devices.



TC-113—February 29, 1940

"The Food, Drug, and Cosmetic Act makes no provision for the submission of applications to the Secretary in connection with devices. However, if this device is used as a part of a combination package; i.e., a package containing the device and a drug, it may be necessary to submit an application to the Secretary in connection with the drug when used in the manner directed for this device.

"We also wish to point out that Section 502(j) of the Food, Drug, and Cosmetic Act, prohibiting the distribution of dangerous drugs or devices, is now in effect. If the directions for use which accompany your client's device call for the administration of any drug, \* \* \* new or old, in a manner which is dangerous to health, the device may be subject to legal action under this section of the Act."

### RUBBER NIPPLES

Rubber nipples are not regarded as subject to the Act, but labeling claims could render them subject.

TC-114—February 29, 1940

"The visitor inquired if rubber nipples were subject to the provisions of the new Act. He was told that we did not regard

them as subject but claims made in the labeling could easily bring them within the jurisdiction of the Act."

### YELLOW PHENOLPHTHALEIN

Method of declaring "Yellow Phenolphthalein" as an ingredient in a drug product is outlined.

TC-115—February 29, 1940

Correspondent's letter deals with the declaration of yellow phenolphthalein upon the labels of drug products containing that substance.

"As you state, 'Yellow Phenolphthalein' is quite different from the phenolphthalein described in the United States Pharmacopoeia. The mere name 'Yellow Phenolphthalein' may, however, not be sufficient to indicate to the purchaser that this is a different article from 'Phenolphthalein.' For the present, the Administration will not

take exception to the use of the term 'Yellow Phenolphthalein' as a designation for this article if the parenthetical statement 'Not U.S.P.' immediately follows the designation. This is not to be considered as a requirement under Section 501(b) relating to articles purporting to be drugs, the names of which are recognized in official compendia but differing in strength, quality or purity from the official standards; but rather as a means of warning the purchaser not to confuse this drug with the official article of a somewhat similar name."

### CODE LABELING—LABELING OF CHEMICALS FOR TECHNICAL USE

There will be no objection to the use of "code labeling" where article is labeled "Not for Food, Drug or Cosmetic Use," etc., provided article is sold in good faith for technical use only. In general, articles not intended for and not used in food, drugs, or cosmetics are not subject to the Act.

TC-116—February 29, 1940

Correspondent's inquiry involves the use of "code labeling" on individual chemicals, mixtures of chemicals, and in some instances private formula pharmaceutical preparations. In some cases the materials are supplied for strictly chemical purposes.

"\* \* \* There will be no objection under the provisions of the Food, Drug, and Cosmetic Act to the use of 'code labeling' where the article is conspicuously labeled as 'Not for Food, Drug or Cosmetic Use,'

or 'For Technical Use Only,' or 'For Industrial Use Only,' provided the article is sold in good faith for technical use only and in fact is so used. If such materials are sold for drug purposes, whether or not the 'code' designation would violate the terms of Section 502(a) with reference to being 'false or misleading in any particular,' or any other section of the Act, would depend upon the circumstances in each particular instance. Obviously, no general rule in this connection can be laid down.



"If the article is a drug and is labeled 'For Manufacturing Use Only,' this would serve to exempt it from the requirements of clause (1) of Section 502(f), which requires that the label bear adequate directions for use, provided the conditions of Regulation (b)(3) under Section 502(f) are complied with.

"The exemption under Section 503(a) contemplates either a maintenance of ownership of the article during its interstate transportation to the establishment where it is to be labeled or packed or a definite agreement between the shipper and the consignee as to the packaging and labeling of the article prior to its distribution to consumers. Under such circumstances the article might bear a code labeling and be exempt from the requirements of Sections 501(b) and 502(b)(d)(e)(f)(g), provided the requirements of the regulation

under Section 503(a) are complied with. This exemption would not, of course, apply to raw materials intended to be used in manufacturing processes. \* \* \*." (See TC-81)

"It may be stated that, in general, articles not intended for and not used in food, drugs, or cosmetics are not subject to the provisions of the Act. If labeled 'U.S.P.' or 'N.F.' it would be assumed that the manufacturer was thereby offering them for medicinal use, even though they were sold to a technical manufacturer. If not intended for medicinal use and sold in good faith for technical uses only, our suggestion would be that the references to the United States Pharmacopoeia and National Formulary be omitted and the article be specifically labeled 'Not For Food Use' ('Cosmetic Use' or 'Drug Use' as the case may be)."

### "MERCUROCHROME"

"Mercurochrome" is a trademarked, not a common, name. The chemical term dibromoxymercurifluorescein sodium should be used in the ingredient statement.

TC-117—February 29, 1940

"We can readily understand your surprise that this Administration should consider the chemical term 'dibromoxymercurifluorescein sodium' as the 'common name' for the product generally called 'mercurochrome.' It may be pointed out that the term 'mercurochrome' is trademarked and its use, therefore, is limited to the owner of this trademark. In this sense the term 'mercurochrome' is, therefore, not 'common.' If and when the same compound is manufactured by a firm other than the one at present manufacturing it, presumably it

may not be sold as 'mercurochrome.' The chemical name, on the other hand, is common property and we think should for that reason be used in listing the article as an ingredient of any drug. There would, of course, be no objection and it would, no doubt, be in the interest of informing the purchaser if the designation by the chemical name is followed with a parenthetical statement to the effect that the particular brand of dibromoxymercurifluorescein sodium used is mercurochrome, if this is the case."

### CONFECTIONERY—DRIED EGG PRODUCT

The labeling of confectionery containing dried egg product should reveal the dehydrated nature of that ingredient.

TC-118—February 29, 1940

Correspondent requests information on the labeling of confectionery and baked goods containing a dried egg product as one ingredient.

"We have held that in the case of baked products the dried whole egg, dried egg albumen, and dried egg yolk can be declared by the use of the terms 'eggs,' 'egg white' (egg albumen), and 'egg yolk,' respectively. This conclusion is based on the theory that in baked products an egg ingredient, whether it originally be fresh, frozen or dried, has lost the characterizing differences of

moisture and temperature of the original egg products. Of course, if it should develop that this method of declaring the egg ingredients in baked products results in withholding information from consumers to which they are entitled under the Act, it would be necessary to rescind this opinion, and the industry would be so advised.

"In the case of confectionery, the same considerations would not be uniformly applicable. You realize, of course, that the various products included under the generic term 'confectionery' are prepared in many different ways. While some are heat-



ed to an extent approaching the baking process for cakes or breads, other items of confectionery are not heated in their preparation or are heated very little. We cannot escape the conclusion, therefore, that if dried egg products be used in the preparation of confectionery the labels should in-

dicate the dehydrated nature of the egg products. Thus, for example, if dried egg white be used in a marshmallow we believe that the terms of the Act would require the ingredient list to include this ingredient as 'Dried Egg White.' "

### FROZEN DESSERTS—INGREDIENT STATEMENT

Frozen desserts other than those theretofore exempted from requirements of Section 403(i)(2) must bear ingredient statement. The exempted product used as an ingredient may be listed by its common name.

TC-119—February 29, 1940

Correspondent requests a written ruling in regard to the exemption of frozen products from the requirement that ingredients be shown on the label.

"You refer to the letter from the Department dated May 4 to the ice cream manufacturers, temporarily exempting certain frozen products having common or usual names from the listing of ingredients pending the formulation of a standard." (TC-64). "That ruling specifically exempted 'Ice Cream,' 'Frozen Custard,' 'Iced Milk,' 'Milk Sherbet,' and 'Iced Sherbet.' It will be apparent, therefore, that it did not include frozen confections or other frozen products of which one of the above-mentioned articles is merely an ingredient.

"You ask whether, if one of the products exempted by reason of the Department's letter of May 4 is covered with a chocolate-

flavored coating and is sold in package form, it will be necessary to list the ingredients on the label. The answer is 'Yes.' However, the ingredient which is one of the frozen products named in the exemption letter could be designated in the ingredient list on the label of the chocolate-flavored confection merely by the name stated in the Department's letter of May 4. For example, if a product consists of ice cream coated with a coating composed of cocoa, chocolate, and hardened cocoanut oil, it could be labeled with the following ingredient list: 'Ice cream coated with cocoa, chocolate, and hardened' cocoanut oil.'

"The form of labeling mentioned above is, of course, subject to possible change when standards have been promulgated for ice cream and for chocolate products."

### COAL-TAR COLOR MIXTURES FOR FOOD USE

An exemption from Section 403(i)(2) of coal-tar color mixtures for food use is denied. A sample label complying with the Act is described.

TC-120—February 29, 1940

Letter dated February 23, 1940, signed by the Secretary of Agriculture.

In a letter dated January 4, 1940, you requested, on behalf of a group of manufacturers of mixtures of coal-tar food colors, that consideration be given to the promulgation of an exemption under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act, exempting certified mixtures of coal-tar colors from bearing labels setting forth the individual names of the colors and diluents used in such mixtures. Your original request was supplemented by your letter of February 12, 1940, and on February 19 by statements presented orally to a committee duly designated for the purpose.

"I have reviewed all of the data submitted by you and the report and recommendations of the said committee and fail to find

substantial evidence, sufficient to justify a regulation exempting your product as requested.

"However, as provided for by the Act, regulations have been promulgated after public hearing, listing eighteen coal-tar colors which were found to be harmless and suitable for use in coloring food. It is my understanding that the coal-tar colors contained in the mixtures in which you are interested are all from batches individually certified by the Food and Drug Administration of this Department as provided by the Statute, after samples thereof have been subjected to analysis. These mixtures are prepared from one or more of these certified coal-tar colors with or without diluents. Samples from batches of these mixtures are submitted to the laboratories of the Food and Drug Administration for certification.



These mixtures then have to be individually certified by the Food and Drug Administration after analysis.

"As these mixtures are used in food solely to impart color and their certification discloses their purity and suitability for such use, a consideration of all of the facts now available to us leads to the conclusion that the requirements of Section 403(i)(2) of the Food, Drug, and Cosmetic Act will be met if the containers of such mixtures are labeled:

"(1) with the common name of the color or colors therein, referred to as 'Certified Coal-Tar Color' or 'Certified Coal-Tar Colors'; and

"(2) with the common name of each diluent therein.

"The containers of such mixtures must in addition be labeled as required under the regulations for the listing and certification of coal-tar colors and other provisions of the statute.

"A typical label of such a mixture might read:

One Pound  
Red Rose Shade  
Mixture of  
Certified Coal-Tar Color (or Colors)  
———% Pure Dye  
Sugar, Starch (or name of other  
diluent used)  
Lot No.———  
John Doe & Co.  
Doeville, Tenn.

"Should it later develop that the form of labeling discussed herein either results in deceiving the public or in withholding any substantial information of the kind guaranteed to the consumer by Section 403(i)(2) of the Food, Drug, and Cosmetic Act, the Department reserves the right, on appropriate notice to the industry, to modify this opinion."

### IMPORT PROCEDURE

All importations which are required to be covered by consular invoices must also be accompanied by shipper's declaration on Consular Form 198. Shipments which need not be accompanied by consular invoices must be accompanied by shipper's declaration executed on Form 197.

TC-121—February 29, 1940

Correspondent requests a list of foreign-produced articles on which Consular Forms 197 and 198 may not be required.

"This Administration has published no list of foods or drugs or other items which, when offered for entry into the United States, are not required to be accompanied by an appropriate declaration from the foreign shipper. Specifically, we have not insisted on a declaration on raw or refined sugar, fish, vegetables, fruits, and grains, such as wheat and barley in their natural

state. It is required, however, on articles manufactured, dried, or treated in any manner, such as tea, coffee, cocoa, rice, nuts, crude drugs, and spices \* \* \*. As a general statement, it may be said that all importations which are required to be covered by consular invoices must also be accompanied by shipper's declaration on consular Form 198. Those shipments which need not be accompanied by consular invoices must be accompanied by shipper's declaration executed on Form 197."

### ALCOHOL—CHLOROFORM

All products commonly known as alcohols should be included by expression "any alcohol" in Section 502(e). Glycerin is not commonly regarded as an alcohol.

Manner of declaring alcohol and chloroform described.

TC-122—February 29, 1940

"No list has been prepared naming the alcohols which are to be included by the expression 'any alcohol' in Section 502(e) of the Act. It is our opinion that all products commonly known as alcohols should be included. Glycerin, while scientifically speaking is classified as an alcohol, is not commonly regarded as such."

"We note that \* \* \* you propose to declare the presence of ethyl alcohol and of

isopropyl alcohol in terms of minims per ounce. We direct your attention to Section 502(e)(2) of the Food, Drug, and Cosmetic Act which requires a declaration of the quantity, kind, and proportion of any alcohol contained in a drug. It is our opinion that this requirement is not satisfied by the declaration in minims per ounce, but would be satisfied by a declaration of both ethyl alcohol and isopropyl alcohol in percentage



by volume. (See paragraph (c)(2) under Section 502(e) of the regulations).

"The declaration of chloroform \* \* \*

would be considered satisfactory if it were expressed in terms of minims per fluid ounce."

### OFFICIAL DRUGS—EXEMPTIONS FROM LISTING OF INGREDIENTS

The first phrase of Section 502(e) was intended by Congress to exempt all drugs designated solely by official names from any of the requirements of this section, including the declaration of alcohol.

TC-123—February 29, 1940

"The first phrase in Section 502(e) reads as follows: 'If it is a drug and is not designated solely by a name recognized in an official compendium \* \* \*.' This phrase was intended by the Congress to exempt all drugs designated solely by official names from any of the requirements of this section, including the declaration of alcohol. Thus, one may distribute Basham's Mixture under the title 'Liquor Ferri et Am-

monii Acetatis' without any declaration of alcohol or of the active ingredients, or even a translation of the name to make it intelligible to the general public. If, however, the article is designated as 'Clark's Preparation,' even if it has the exact formula described in the National Formulary, the label must bear a list of all the active ingredients and a quantitative declaration of alcohol. \* \* \*"

### IMITATION FLAVORS—"COMMON OR USUAL NAMES"

Imitation flavors with which the public is familiar, and which are defined in dictionaries, should be listed by their specific names on labels of food flavors and imitations which are subject to Section 403(i)(2).

The listing of other listed ingredients which bear complex chemical names, unfamiliar to public, can serve no useful purpose and may be described as artificial flavor consisting of synthetic esters, ketones, and aldehydes.

TC-124—February 29, 1940

"We have been giving careful consideration to the labeling, under Section 403(i)(2) of the Act, of imitation flavors which contain a large number of individual flavoring ingredients, many of which bear complex chemical names with which most purchasers are unfamiliar. We believe that the Act does not contemplate the listing on the labels of food flavors of such chemical names as acetyl methyl carbinol and ethyl oenanthate, as such names cannot be regarded as the common or usual names of these ingredients. On the other hand, the public is more or less familiar with some of the more common synthetic flavors such as vanillin and coumarin, with the various essential oils such as fennel, cinnamon, clove, bitter almond, etc., with true flavors derived from plant material or fruits such as maple flavor, strawberry flavor, etc., and with such usual ingredients of flavors or imitation flavors as sugar, water, alcohol, glycerol, phosphoric acid, citric acid, and tartaric acid. We are of the opinion that all such substances with which the public is more or less familiar and which are defined

in dictionaries should be listed by their specific names on the labels of food flavors and imitations which are subject to the requirements of Section 403(i)(2).

"The listing of the other ingredients referred to above, which bear complex chemical names and with which the public is unfamiliar, can serve no useful purpose and such names cannot be regarded as the common or usual names of the ingredients within the meaning of the Act. Under these circumstances it is not our purpose to take regulatory action against imitation food flavors which describe such constituents as ethyl oenanthate and other esters bearing unfamiliar names, discetyl and other ketones bearing unfamiliar names, and heliotropin and other aldehydes bearing unfamiliar names, as artificial flavor consisting of synthetic esters, ketones, and aldehydes.

"The other constituents referred to above which bear such common or usual names as vanillin, coumarin, clove oil, sugar, water, phosphoric acid, etc., should be listed by their specific names when such of these ingredients as are artificial flavors are referred to as artificial flavors. \* \* \*"



**LEMON PIE OR CAKE—"LEMON EMULSION"**

The presence of "Lemon Emulsion" in lemon pie or cake may be declared as "flavoring." However, if the flavoring contains an unusual solvent or vehicle, a specific declaration is required.

TC-125—February 29, 1940

Correspondent asks whether the labeling of a lemon pie or cake flavored with a "Lemon Emulsion" consisting of oil of lemon, vegetable gums, fruit pectin, glycerin, lemon juice, and water need declare all the ingredients of the flavor.

"In our opinion, it would meet the requirements of Section 403(i)(2) of the new Act if the flavoring mixture mentioned

above is referred to in the labeling merely as 'flavoring' or 'flavor,' as this term is understood to include the ingredients ordinarily used as vehicles or emulsions. However, if some unusual solvent or vehicle is used in the flavoring, it would be necessary, in our opinion, to indicate its presence on the label of the pie or cake, in addition to the declaration of flavor."

**"EGG NOODLES AND CHICKEN"—"FLAVORING"**

"Flavoring" is sufficient ingredient declaration to cover onions and celery which are boiled with chicken during the preparation of the broth and subsequently removed.

TC-126—March 7, 1940

Comment was requested on the label for a brand of egg noodles and chicken, the question being "Should onions and celery which were boiled with the chicken during the preparation of the broth and subsequently removed be declared by name in the list of ingredients?"

"If \* \* \* the onions and celery are not contained in the product except in the form of flavoring obtained by previously boiling the onions and celery in the broth and subsequently straining it, we would not be inclined to insist that the specific names of the vegetables be listed but that the word 'flavoring' be used in the ingredient list to cover them."

**CANNED GRAPEFRUIT—LABEL DESIGNATIONS**

Canned broken grapefruit should be labeled to show that it consists of broken fragments, and the term "Standard Grade" is not a satisfactory substitute.

"Fancy Hearts of Florida Grapefruit" is not suitable for canned whole segments or sections of grapefruit.

TC-127—March 7, 1940

Regarding the use of the term "Standard Grade" instead of the word "Broken" on canned grapefruit containing broken sections.

"It is our opinion that canned broken grapefruit should be labeled with a conspicuous statement showing that it consists in whole or in part of broken sections, and we do not think that the term 'Standard Grade'

is a satisfactory substitute for such labeling."

Regarding the use of the designation "Fancy Hearts of Florida Grapefruit" for canned whole segments or sections of grapefruit:

"We are not aware of any edible part of the grapefruit which could be appropriately described as the 'heart' and under the circumstances it would appear to us that the proposed designation is not suitable."

**SURGICAL SUTURES—USE OF CERTIFIED COLOR**

Since surgical sutures are classified as drugs, certified colors other than those certifiable for external use only could apparently be used without violating the Act.

If colored gut sutures are sold, label must show difference from the pharmacopoeial product.

TC-128—March 7, 1940

Correspondent requests information about certified dyes for use in connection with surgical sutures.

"We are enclosing for your information a list of coal-tar colors which are certifiable as harmless and suitable for use in foods, drugs, and cosmetics, for drugs and cos-



metics, and for externally applied drugs and cosmetics only. This Department is not certifying colors especially for use in connection with surgical sutures, but since such products are classified as drugs, certified colors other than those certifiable for ex-

ternal use only could apparently be used without violation of the Act.

"If you intend to sell colored gut sutures, however, these should be named in such a manner as to be clearly distinguished from the pharmacopoeial product."

---

### "KAMALA"

The drug kamala is no longer regarded as being of value in the treatment of worms in poultry.

TC-129—March 7, 1940

"\* \* \* this Department no longer regards the drug kamala as being of any value in the treatment of tapeworm infestation of poultry, nor as a treatment for any other species of worms which infest poultry. In

view of this fact this Administration, which is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, cannot sanction any claims for tapeworms for your product containing kamala."

---

### LOLLIPOPS CONTAINING ASPIRIN

Lollipops containing aspirin may be marketed if properly labeled to differentiate them from candy and to insure use only under physician's direction.

TC-130—March 7, 1940

"We refer to your visit to the Administration on November 23 in connection with the proposed marketing of your drug product containing aspirin.

"This product was to be marketed in the form of a lollipop for use principally by physicians, particularly in connection with the treatment of patients after tonsil operations. At that time we advised you that in our opinion the product would fall in the category of confectionery because of its similarity to lollipops, and consequently would have to be regarded as adulterated because of the presence of aspirin. You were advised that there would be no objection to changing the form of the article and

placing a lozenge containing aspirin on the market under a drug label through drug channels. Since that time the Administration has had occasion to give renewed consideration to aspirin-containing drugs in the form of lollipops intended for the same purpose, and in the light of more recent interpretations of the new Act we are not at this time objecting to the manufacture of these preparations in the form of lollipops—that is, with the sticks—provided they are not labeled in any way to suggest that they are lollipop 'candy' and provided further they are prominently labeled in such a way as to insure their use only by or under the directions of physicians."

---

### ABSORBENT COTTON

Manner of labeling absorbent cotton to show difference from Pharmacopoeial standard is discussed.

TC-131—March 7, 1940

Correspondent states his understanding of the Administration's opinion regarding the labeling of absorbent cotton which differs from the Pharmacopoeial requirements in fiber lengths.

"Your statement is essentially in accordance with our ideas of the way in which the cotton should be labeled to take ad-

vantage of the exemption provided by Section 501(b) of the Food, Drug, and Cosmetic Act. In addition to a statement of the maximum percentage of fibers below  $\frac{1}{4}$  inch in length, there should also be a statement of the minimum percentage of fibers not shorter than  $\frac{1}{2}$  inch if that figure differs from the percentage (60) stated in the Pharmacopoeia. \* \* \*

---

### TABLET MANUFACTURE—ISOPROPYL ALCOHOL

There is no objection to the use of isopropyl alcohol in the granulating of materials to be used in tablets.



TC-132—March 7, 1940

Inquiry concerns the use of isopropyl alcohol in the manufacture of medicinal tablets.

"We understand that you propose to use isopropyl alcohol in granulating the chemicals before compressing them into tablets and that all the alcohol will be evaporated by heat and none will remain in the finished product. The important thing in connection with the distribution of a tablet is the com-

position of the tablet and the claims which are made for it. It does not appear to us that the use of some solvent at one point in the manufacture would in any way affect the finished article if this solvent is subsequently removed by evaporation. We see no objection at the present time to the use of isopropyl alcohol in connection with the granulating of materials to be used in tablets."

### "BOUILLON"—"BOUILLON CUBES"—"GRANULATED CHICKEN BOUILLON"

Propriety of these terms.

TC-133—March 7, 1940

"We do not feel that the label \* \* \* for 'Granulated Chicken Bouillon' is appropriate. This product is of the same composition as the chicken bouillon cubes. We judge, however, that it is not in cube form. In our consideration of the appropriateness of the designation 'bouillon cubes' in the absence of standards, we have not raised objection to such designation on products containing wheat protein derivative when properly labeled to show the artificiality of the flavor contributed by this derivative."

"In the case of 'chicken bouillon cubes' we have regarded such name as appropriate if sufficient chicken extractives are present in addition to give definite chicken characteristics, especially flavor. This position was taken in view of the long recognition of the term 'bouillon cube' for this type of product containing large amounts of salt and so-called plant extract (wheat protein derivative in unpurified form). We do not feel that recognition of the term 'bouillon cube' should be the basis for the application of the word 'bouillon' to these com-

binations containing wheat protein derivative. 'Bouillon' is a very definite name associated with stock made from a definite variety of meat or designated raw material. It is quite possible that standardization might deny the name 'bouillon' to these cubes. Under the circumstances we feel that the designation 'Granulated Chicken Bouillon' is inappropriate. If it is desired to designate this product as 'Granulated Chicken Bouillon Cube' or 'Chicken Bouillon Cube Granulated' we are not disposed to offer objection at this time."

"We believe further that designation of the food product made by dissolving these cubes in water by the names 'bouillon,' 'consomme,' and similar terms which have a definite meaning to the consuming public, is unwarranted. We are therefore taking exception to the directions on the label for chicken bouillon cubes, where the statements 'For Cup Bouillon' and 'Consomme' appear. These words should be deleted from the directions. The list of uses for the product might be headed by the word 'Directions.'"

### "TOMATO SAUCE"—"BEANS WITH PORK"

Label reading "Beans with Pork in Tomato Sauce" is satisfactory without listing the ingredients of the sauce if the sauce conforms to usual tomato sauce.

If, however, the packing medium is not such tomato sauce, a declaration of ingredients is necessary. Water, if used, must be included.

TC-134—March 7, 1940

"You are correct in your understanding that labels reading 'Beans with Pork in Tomato Sauce' will be regarded as satisfactory without listing the various ingredients of the sauce, provided the tomato sauce conforms in composition with the usual tomato sauce used for that purpose and subject, of course, to reconsideration if it develops that consumers are being denied

information to which they are entitled.

"If, however, mature beans, such as red kidney beans which you mention, are packed merely in sugar, water, and salt instead of in sauce, then it is necessary to list the ingredients of the packing medium. In regard to the declaration of the sweetening ingredient, the presence of sugar may be expressed as 'Sugar' and the presence of dextrose may be expressed as 'Dextrose' or



'Corn Sugar.'

"\* \* \* However, in the case of the \* \* \* label you submitted, the designer of the label has apparently elected to list the ingredients, since instead of naming the type of sauce the label states 'Prepared with

Brown Sugar, Molasses, Salt, Starch, Pork,' giving the impression that all of the sauce ingredients are named. If water as such is added along with the ingredients enumerated, then, in our opinion, water should be declared also."

#### "LIMA BEANS"—"BUTTER BEANS"

Preferable to couple terms "Lima Beans" and "Butter Beans" on label, since "Lima Beans" may not be known as "Butter Beans" in different sections of country.

TC-135—March 7, 1940

Correspondent raises a question as to the propriety of the term "Butter Beans" for canned lima beans when sold in a part of the country where lima beans are better known as "Butter Beans."

"We have not been disposed to object to the use of the term 'Butter Beans' in the case of specific consignments sold in such parts of the country where the term is

understood, but since it may be impossible for a canner to forecast the ultimate destination of all of his pack of lima beans, it would be well, in our opinion, to couple the two names 'Lima Beans' and 'Butter Beans' together on the label. For example, the name 'Lima Beans,' which is probably more widely understood, might form the main name of the article, followed by the name 'Butter Beans' in parenthesis. \* \* \*

#### ARSENIC—FLUORINE—LEAD

Tolerances for arsenic, fluorine, and lead in chemicals used in small quantities in foods.

TC-136—March 7, 1940

Correspondent inquires regarding permissible limits of various impurities, such as arsenic, fluorine, and lead, in chemicals used in small quantities in the preparation of foods.

"The Administration, in the enforcement of the old Food and Drugs Act, never announced formal tolerances for these substances in foods since no authority existed in the old law for so doing. The law, as you know, merely classed a food as adulterated if it contained any added deleterious ingredient which might render food injurious to health, leaving it a question of fact in each case that might arise as to whether the food was adulterated.

"We have, of course, as you know, informally announced certain tolerances for arsenic, fluorine and lead existing in spray residues on fresh fruits, these being 0.01 grain arsenic per pound, 0.02 grain of fluorine per pound, and 0.025 grain of lead per pound. The new Act contains practically the same provision as indicated above but, in addition, authorizes the Secretary to promulgate tolerances in the case of deleterious substances added to food where the addition cannot be avoided by good manufacturing practice or where such substance is required in the production of the food. The new Act also prohibits added deleterious ingredients in foods in any amount when their addition is not required

in the production of the food or can be avoided by good manufacturing practice.

"As yet there has been no opportunity to formulate tolerances under the new Act for substances you mention since the Public Health Service, to whom Congress assigned the responsibility of studying the question of the harmfulness to health of spray residues, has not yet concluded its investigations on arsenic and lead. It is not possible at this time, therefore, to forecast the limits that may be imposed in the case of chemicals used in foods in small amounts or whether such limits will be different from those proposed in the case of the final food product itself, nor can we forecast that the substances in all instances can be permitted in any amount.

"It is our opinion that for the time being we must continue to advise that, wherever possible, complete elimination of arsenic, fluorine, and lead in chemicals to be used in foods be strived for, particularly in the case of lead. In the case of arsenic, we believe that in chemicals to be used in foods it should be held to 0.01 grain per pound or lower. In the case of certain phosphates used as ingredients in foods whereas a few years ago relatively large fluorine contents were encountered, rapid strides have recently been made in reducing the fluorine content to a point closely approaching the above indicated tolerance of fluorine as spray residue."



### "PORK AND BEANS"—LABEL ARRANGEMENT OF INGREDIENT NAMES

In view of general understanding of public of the canned product prepared from beans with lesser amount of pork, the Administration has not insisted on word "Beans" coming first.

TC-137—March 7, 1940

"\* \* \* We have issued no specific ruling regarding the arrangement of the words 'Pork and Beans' or 'Beans With Pork.' In general, of course, the ingredient which predominates should be named first. However,

because of the general understanding of the consuming public over a period of a great many years of the canned product prepared from beans with a lesser amount of pork, we have not insisted upon the word 'Beans' coming first."

### "MINT TEA"—DESIGNATION OF

The term "Mint Tea" is vague. The name might be used if in connection therewith a statement showed that the product is a blend of tea and mint. The reference to the source of the mint should be geographically accurate.

TC-138—March 7, 1940

Correspondent's letters discuss the labeling of a product designated "\* \* \* Mint Tea" and raise further question with regard to the designation of the kind of mint used in making the product.

"\* \* \* the Federal Food, Drug, and Cosmetic Act requires that foods bear their common or usual name, as well as a list of the ingredients when fabricated from two or more foods, a declaration of the quantity of contents, and the name and address of the manufacturer, packer, or distributor. These mandatory statements should appear conspicuously on the label and this can be best accomplished by their appearance on the main display panel or panels.

"We feel that the name 'mint tea' is more or less vague, as to the true identity of the product. It might be taken by some to mean a tea-like product made from mint and by others a real tea with mint flavor. However, the name might be used if in direct connection therewith a statement appeared showing that the product is a blend of tea and mint. This statement would also serve as the statement of ingredients. It would not be appropriate to refer to the product as 'Kentucky mint' unless the mint originated in Kentucky. Mint originating in nearby states would not be entitled to be designated 'Kentucky mint.'"

### PYROLIGNEOUS ACID—"SMOKE"

Product sold as substitute for smoke required, under Section 403(i), to be designated as pyroligneous acid, its common name.

TC-139—March 7, 1940

Correspondent's letter relates to the labeling of a product manufactured and sold under the name of "\* \* \* Substitute for Smoke."

"This product, when shipped in interstate commerce, is subject to the requirements of the Federal Food, Drug, and Cosmetic Act \* \* \*. You will note that Section 403(i)(1) provides for a statement on the label of the

common or usual name of the product. It is our opinion that the common or usual name of a product such as you describe would be 'artificially colored pyroligneous acid.'

"In accordance with the provisions of Section 403(i)(2) the ingredients of the preparation, that is, pyroligneous acid and caramel coloring, should be conspicuously set forth on the label. \* \* \*"

### SPECIALLY DENATURED ALCOHOL

Some denaturants may be active ingredients. The Act requires a statement of the quantity or proportion of the absolute alcohol contained in drug product; it is not satisfactory to give the amount of specially denatured alcohol.

TC-140—March 7, 1940

Correspondent asks if the denaturants in specially denatured alcohol are to be regarded as active ingredients.

"A number of the formulas for specially denatured alcohol have been devised for the purpose of partially manufacturing a drug product. The alcohols contain some



of the ingredients which are required in the finished product but not all of the ingredients. Other denatured alcohols contain ingredients which are added for the sole purpose of making them non-potable but which may under certain conditions be regarded as active. In view of this fact, the question of whether or not the denaturants are active ingredients must be determined by the

particular denatured alcohol formula used and the use for which the resulting product is intended.

"The Federal Food, Drug, and Cosmetic Act requires a statement of the quantity or proportion of the absolute alcohol contained in the drug product. It is not satisfactory to give the amount of specially denatured alcohol. \* \* \*"

### DRIED BEANS, PEAS AND LENTILS

Dried beans, dried peas, and dried lentils in 100-110 pound bags should bear, pursuant to the marking requirements of Section 403, labels containing name and place of business of manufacturer, etc., and statement of quantity of contents in avoirdupois pounds. Dry edible beans in large bags will be classed as food in package form.

TC-141—March 7, 1940

Correspondent inquires whether dried beans, dried peas, and dried lentils, packed in burlap bags containing 100 pounds or 110 pounds, are subject to the marking requirements of Section 403 of the Act.

"In our opinion, dried beans, dried peas, and dried lentils packed in burlap bags containing 100 pounds or 110 pounds net weight when brought within the jurisdiction of the Food, Drug, and Cosmetic Act, should bear labels containing the name and place of

business of the manufacturer, packer, or distributor and an accurate statement of the quantity of contents in terms of weight expressed in avoirdupois pounds."

"\* \* \* Dry edible beans, in large bags, as well as in small bags of one, two or three pounds, will, under the new Act be classed as food in package form and will be required to bear the mandatory label information, that is, the net weight; the name and address of the grower, packer, or distributor, and the name of the article."

### FRUIT JUICES—CANNED GRAPEFRUIT JUICE—SWEETENING INGREDIENT—"NATURAL"

Since definitions and standards of identity for fruit juices have been promulgated, labels for sweetened grapefruit juice should refer specifically to the particular sweetening employed. The term "Natural" should be reserved for fresh juice or juice which has been kept without intervention of any process of heat treatment.

TC-142—March 7, 1940

Correspondent's letter of January 10, 1940, inquires about the proper method of labeling canned grapefruit juice to which a sweetening ingredient has been added.

"As yet no consideration has been given to the formulation of definitions and standards of identity for grapefruit juice and other fruit juices, nor have they been temporarily exempted from the requirements of Section 403(i)(2) of the Food, Drug, and Cosmetic Act under authority of Section 902(a)(2). Therefore labels for sweetened grapefruit juice, to which you particularly refer, should bear a specific reference on the label to the particular sweetening employed,

as for example, 'sugar added' in the case of sugar (sucrose), or 'dextrose added' in the case of the addition of that sweetening ingredient. There is, of course, no objection to the retention of the word 'sweetened' on the label in addition to the name of the particular sweetening substance."

"One of your labels for canned grapefruit juice bears the legend 'Natural—Unsweetened.' We have consistently questioned the propriety of the designation 'Natural' for canned grapefruit juice subjected to the usual heat treatment. We feel that this term should be reserved for fresh juice or juice which has been kept without intervention of any process of heat treatment."



**PURE FRUIT FLAVORS—USE OF “FIXATIVES”**

The use of “fixatives,” artificial flavors, must be declared on label.

TC-143—March 7, 1940

Inquiry concerns the question of the addition of 1/10 of one per cent of “fixatives” to pure fruit flavors. Numerous expressions of concern from fruit growers and packers have reached us regarding the effect on the industry if fruit flavor manufacturers are not permitted to add this small quantity of the so-called “fixatives” to true fruit flavors without labeling the resulting products as imitations.

“The fixative referred to unquestionably is one or more of the synthetic chemical flavoring materials quite often used, and quite properly when announced on the label, in place of actual fruit to impart an artificial fruit flavor. It seems clear that the berry growers and packers have not been fully advised by flavor manufacturers in regard to the actual nature and significance of these fixatives. As a matter of fact, the flavoring

strength of these artificial fixatives or artificial ‘fixative flavors’ is enormously greater than the flavoring strength of an equal quantity of flavor derived from fruit, and their addition greatly reduces the cost of manufacture. With these facts made clear, it would be apparent to fruit growers, I am sure, that what really happens when a fixative is added in an amount even as small as 1/10 of one per cent is that it merely substitutes for a much larger quantity of actual fruit which otherwise would have been purchased and made into true fruit flavor. From this 1/10 of one per cent of artificial fixative it is, of course, only a few more steps to the complete substitution of artificial flavors, if the artificial were to be permitted to masquerade as the genuine, as would be the case of course, if the inclusion of the fixative without proper label disclosure could and would be permitted. \* \* \*

**CAFFEINE IN SOFT DRINKS SUCH AS “COLA” BEVERAGE**

No tolerance has been announced for caffeine in soft drinks, but its addition to such drinks has been discouraged.

TC-144—March 7, 1940

Correspondent indicates purpose to manufacture a flavor for making a “cola” beverage.

“This Administration has announced no ‘tolerance’ for the amount of caffeine that may be added to such a product. We have consistently discouraged the addition of caffeine in any amounts to soft drinks which

may be, and of course often are, consumed by young children. Parents may not always desire them to consume caffeine-containing preparations. Whether or not caffeine is present in a soft drink in an amount which may constitute a deleterious ingredient which may render the article injurious is a question of fact in each case.”

**DIGLYCOL STEARATE IN FOOD**

In the absence of conclusive evidence of the harmlessness of diglycol stearate, it should not be used in food.

TC-145—March 7, 1940

Communication deals with the propriety of the use of diglycol stearate as an emulsifying agent in a food product.

“While we have not studied the toxicity of diglycol stearate in our own laboratories, a review of the literature strongly indicates that the compound is a toxic substance. It is our opinion that in the absence of con-

clusive evidence of the harmlessness of the article, it should not be used in food. We are not in a position to deal responsively with other phases of this matter, such as the labeling of the food, because we do not know the exact composition of the article to which its use is proposed, nor the labeling under which it would be sold.”

**SOAP—SHAMPOOS, SHAVING CREAMS, ETC.**

The exemption of soaps from the definition of cosmetic in Section 201(i) does not apply to shampoos and shaving creams, even though the article be essentially soap and the word “soap” be inserted in the name of the product.

If a soap bears representations which make it a drug under the Act, the product must conform to the drug provisions of the statute.



TC-146—March 7, 1940

"Soap sold as such unquestionably is exempted from regulation under the Act as a cosmetic. This is true whether the product be toilet or shaving soap. It is our judgment, however, that this exemption does not apply to shampoos, to shaving creams, or to any other cosmetic, except soap, even though the article under such nomenclature be essentially soap. I think the reason for this position is obvious. There are shampoos on the market which are not soap and there are shaving creams on the market which are not soap. Such products are subject to the cosmetic provisions of the Act."

"\* \* \* it is our opinion that an article

described as a shampoo is not a soap within the meaning of the exemption contained in Section 201(i) of the Act and that the insertion of the word 'soap' in the name of this product will not entitle it to the exemption provided for soaps. \* \* \*"

"In this connection you will note that soap is exempt only from the provisions of the statute applicable to cosmetics. No mention is made in the law exempting such products from any other provisions. Certainly if a soap bears representations which make it a drug within the meaning of the statute the product must conform with the drug provisions of the Act. \* \* \*"

### "HONEY"—DESIGNATION AS "PEACH BLOSSOM"

A honey may be labeled with the name of a plant or blossom provided the particular plant is the chief floral source of the honey.

TC-147—March 7, 1940

Correspondent inquires as to the permissibility of using the term "Peach Blossom Honey" on labels for honey produced in the Georgia peach belt.

"We have always held that a honey may be labeled with the name of a plant or blossom provided the particular plant is the chief floral source of the honey. Consequently, if a honey producer is in a position to know that peach blossoms constitute the chief floral source of honey which he markets, that particular honey may be labeled 'Peach Blossom Honey.' However, we are concerned about the practical difficulties in the way of determining this. The period of bloom of peach trees is of course very

short, and, therefore, the amount of honey derived from that particular blossom would be very little as compared with the total output of honey during the season. This would seem to be true not only because of the briefness of the blossoming season but also because of the earliness of the blooming period, when bees may be showing little or no activity. We note, however, the statement in your letter that honey bees are seen in commercial orchards in great abundance in Georgia during the normal peach blossoming time, so that it might be possible for a honey producer to take from his hives at the conclusion of the peach blossoming period a limited amount of 'Peach Blossom Honey.'"

### COFFEE—"JAVA-MOCHA BLEND"

The term "Java-Mocha Blend" for coffee is appropriate only if the product is composed 100 per cent of those two coffees.

TC-148—March 7, 1940

Correspondent requests information on the appropriateness of the designation "Java-Mocha Blend" on a coffee bag which is to be used for coffee not containing 100 per cent of these two coffees.

"Under the provisions of the Federal Food, Drug, and Cosmetic Act, \* \* \* it is regarded as constituting misbranding to designate a coffee as 'Java and Mocha Blend' which, in fact, contains coffees other than of these two varieties. In this connection your attention is called to the enclosed Food Inspection Decisions 82 and 91. These were issued in connection with the enforcement of the Food and Drugs Act of 1906

but, because the general misbranding provisions of the new law are analogous to those of the old law, the decisions are still regarded as in effect. The trade mark in the center of the labeling, bearing the words 'East Indies Coffee Growers,' is also regarded as inappropriate on packages containing coffees not grown in the East Indies."

NOTE: The pertinent part of Food Inspection Decision 82 which relates to the matter discussed is to the effect that the term "Java Coffee" should be restricted to the coffee (*Coffea arabica*) grown on the island of Java. Coffee from Padang, Celebes, and Sumatra, or other Dutch East Indies



coffees, are not "Java Coffee." Such coffees can appropriately be called "Padang Coffee," "Celebes Coffee," and "Sumatra Coffee," respectively.

Food Inspection Decision 91 includes a

statement to the effect that the term "Mocha" should be used only on coffee which is produced in that district of Southern Arabia known as "Yemen."

### EGG ALBUMEN—DENATURING FOR TECHNICAL PURPOSES

In the selection of a denaturant to render technical egg albumen unfit for human consumption and therefore not classified as a food, the product added should render the food obviously inedible by some effect on the senses and should prevent the use of the technical product in the manufacture of other foods.

TC-149—March 7, 1940

Correspondent's letter deals with the subject of denaturing dried albumen for technical purposes.

"This Administration has issued no specific directions for denaturing technical egg albumen to make it obviously unfit for human consumption and therefore not classifiable as a food product, amenable to the provisions of the \* \* \* Act. In the selection of a denaturant, from the point of view of the law, the product added should render the food obviously inedible by some effect on the senses and should be present in such quantity as to prevent the use of the technical product in the manufacture of other

foods. At the same time the denaturant should be so chosen as not to interfere with the technical processes in which the product is to be used. I think you appreciate, from these circumstances, that the question of the choice of a denaturant is almost invariably one to be decided on the basis of the conditions in each individual case. We have seen the use of dyes of very brilliant hue prove satisfactory in some instances. Of course these dyes must not be of a shade simulating egg color. In other instances highly aromatic, non-volatile, objectionable smelling substances have proved satisfactory. \* \* \*

### CANNED TOMATOES—"SOLID PACK"

The term "Solid Pack" may be used in addition to the mandatory labeling provided by the standard of identity, if the term is true, and if it is so placed that it does not detract from the conspicuousness of the required information, thus rendering the article misbranded under Section 403(f).

TC-150—March 7, 1940

Correspondent states that the term "solid pack" applies to whole peeled and cored tomatoes with either a small amount of the actual juice of these tomatoes put in the can or none at all. The can thereby contains only the whole tomatoes, as noted. Request is made as to whether this phrase may be used on canned tomatoes.

"The standard of identity promulgated for canned tomatoes to which you refer specifies the labeling which must be used

on the product. This does not, however, prevent the addition of other statements which are not false or misleading, provided they are so placed on the label that they do not detract from the conspicuousness of the required information, thus rendering the article misbranded under Section 403(f) of the Act. Specifically we can see no objection to the use of the words 'Solid Pack Tomatoes' on labels of products packed in accordance with the procedure you outline."

### "IMITATION TOMATO PUREE"

The term "Imitation Tomato Puree" must be used, in accordance with Section 403(c), as designation for strained tomatoes lacking the concentration of tomato puree.

TC-151—March 7, 1940

Correspondent raises question with respect to the status of so-called "Strained Tomatoes Slightly Condensed."

"\* \* \* we understand that you \* \* \* de-

sire to continue to pack this product which consists of whole strained tomatoes very slightly concentrated but not brought to the degree of concentration of 'Tomato Puree.' In our opinion, such a product resembles



'Tomato Puree,' and by reason of this resemblance the product purports to be 'Tomato Puree.' The definitions and standards of identity so far promulgated for tomato products recognize an unconcentrated comminuted tomato product under the name of 'Tomato Juice' and recognize comminuted tomato products in differing degrees of concentration under the names 'Tomato Puree' and 'Tomato Paste,' respectively. There is no recognition of an article intermediate between an unconcentrated tomato product and 'Tomato Puree.' Consequently, it is our opinion that the slightly concentrated

article you have in mind may have no legal status except as provided for under Section 403(c) of the Food, Drug, and Cosmetic Act, the provision dealing with imitations. We suggest, therefore, that in the manufacturing process you continue the concentration to at least 8.37 per cent salt-free tomato solids, producing an article conforming to the standards for 'Tomato Puree' which can be labeled as such. The only other alternative which in our opinion would insure a legal article would be to label your present product 'Imitation Tomato Puree.'"

### **TOMATO PASTE—"SALSA DI POMIDORO"**

The term "Salsa di Pomodoro" constitutes a foreign name for tomato paste, necessitating, pursuant to subparagraphs c (1) and (2) of the regulation under Section 403(f) of the Act, that the label contain mandatory label statements in Italian.

TC-152—March 7, 1940

Correspondent's letter deals with the use of the name "Salsa Di Pomodoro" on one panel for a tomato paste label.

"\* \* \* We can only call your attention to the regulation under Section 403(f), Subparagraphs c (1) and (2). Subparagraph c (2) states that if the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language. The designation 'Salsa Di Pomodoro' is certainly a repre-

sentation in a foreign language and directs the attention of consumers of Italian lineage to the product. Since such consumers may not understand English, it is the intent of this provision of the Act that they be furnished the mandatory label information in the language they understand. We are disposed to believe the requirements would be met by making one panel all Italian and the other panel all English. At least the panel which bears the name 'Salsa Di Pomodoro' should, in addition, bear the net weight statement in Italian and the words 'Distributed by' in Italian. \* \* \*

### **"HONEY AND ALMOND HAND CREAM"—"ALMOND HAND CREAM"**

Cosmetics designated as "Honey and Almond Hand Cream" and "Almond Hand Cream" are misbranded unless those ingredients are present. If the ingredients are not present, the deception inherent in the names cannot be corrected by any such modifying term as "type."

TC-153—March 7, 1940

Correspondent states that the names "Honey and Almond Hand Cream" and "Almond Hand Cream" have been basic items in the cosmetic trade for many years but that the conventional formulas do not call for honey, almond oil, or other derivatives of these substances.

"As you are no doubt aware, cosmetics were not subject to Federal regulation prior to the enactment of the Federal Food, Drug, and Cosmetic Act. One purpose of

this Act is to prevent deception of the consumer, and Section 602(a) provides that a cosmetic shall be deemed to be misbranded if its labeling is false or misleading in any particular. Articles labeled as 'Honey and Almond Cream' or 'Almond Cream' which do not contain these ingredients obviously are misnamed and are misleading to the consumer. We do not believe that the deception inherent in the name can be corrected by means of any such modifying term as 'type.'"



**POULTRY**

Poultry soaked in water from 24 to 36 hours would be adulterated under Section 402(b)(4).

TC-154—March 7, 1940

Correspondent asks whether it is against the law to sell poultry that has been soaked in water from 24 to 36 hours.

"\* \* \* If shipped in interstate commerce such poultry would be amenable to the provisions of the Food, Drug, and Cosmetic Act \* \* \*. One of the adulteration provisions of that law classes a food as adulterated if any substance has been added there-

to or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is. Poultry which had been soaked so that it would absorb water would, in our opinion, be adulterated under this provision and a violation of the Federal Act would occur if shipped in interstate commerce. \* \* \*"

**POULTRY—"MILK FED"—"RETAIL PACKAGE"**

There is no justification for the use of the term "Milk Fed" except when poultry has been fed milk, and not merely a ration containing buttermilk, for a sufficiently extended feed period so that the flesh of the poultry takes on those properties accomplished by milk feeding.

The individually wrapped dressed bird is considered the retail package.

TC-155—March 7, 1940

Regarding the application of the Act to labeling of dressed poultry packages.

"The first question raised is with respect to the propriety of the term 'Milk Fed' when the poultry was fed with a regular feeding ration containing buttermilk.

"We can see no justification for the use of the term 'Milk Fed' except when poultry has been fed milk, and not merely a ration containing buttermilk, for a sufficiently extended feeding period prior to slaughter so that the flesh of the poultry takes on those properties accomplished by milk feeding.

"The second question raised is with respect to whether the individually wrapped bird is the package or the box of poultry containing 12 such wrapped birds.

"We have been disposed in general to regard the individually wrapped poultry as

the retail package and feel, therefore, that it should bear at least as much of the mandatory label information under the new Act as will serve a useful purpose. We would not be disposed to insist that the name of the particular poultry, that is for example, chicken or turkey, appear on the package if it is perfectly apparent to the purchaser what the article is. Furthermore, if the individually wrapped poultry is invariably sold by weight, that is, by weighing at the time of purchase with due allowance for the weight of the container, we would not be inclined to insist upon the net weight statement. We do feel, however, that the purchaser is entitled to know the name of the responsible packer or distributor and that that should appear on the package of the individually wrapped poultry."

**UNDRAWN POULTRY—LABELING REQUIREMENTS**

The labeling requirements of undrawn poultry moving in interstate commerce are discussed, with particular reference to Sections 403(i)(1) and 403(e)(1) and regulation (c) under Section 403(e).

TC-156—March 7, 1940

Letter requests clarification of several questions as they apply specifically to boxes of undrawn poultry moving in interstate commerce.

"1. The term 'net weight' need not be printed in front of the actual net weight if the net-weight statement is in such terms as to be clear to the purchaser or consumer without the addition of the word 'net weight.' For example, if a box containing

fifty pounds of undrawn poultry is conspicuously marked '50 pounds,' the words 'net weight' need not appear in front of this statement, since the term 'pounds' refers only to weight, and since the purchaser understands that the weight statement refers to the actual weight of the food contained in the package.

"2. Section 403(i)(1) of the Federal Food, Drug, and Cosmetic Act requires the common or usual name of the food to appear



on the label. The term 'poultry' is a generic term and as such is not sufficiently specific to meet the requirements of this section of the Act. The common name of the actual commodity packed in the box should be declared, such as, for example, 'Chickens,' 'Turkeys,' etc. However, we have not interpreted the Act as requiring the label designation 'Broilers,' 'Fryers,' or 'Roasters,' as the case may be.

"3. A packer having several stations at which he packs poultry need not give the address of each particular packing point, but may mark all these boxes with the address of his principal place of business or headquarters, provided this statement is not misleading. In this connection your atten-

tion is directed to Regulation (c) under Section 403(e).

"4. Section 403(e)(1) requires the name and place of business of the manufacturer or packer or distributor. The purpose of this section of the Act is to inform the purchaser or the consumer of the person assuming responsibility for that particular food. Since in ordinary commerce the ownership of packages of food changes quite often, it could hardly be expected that the label be changed to show the name and address of each particular owner. A label bearing the name and address of the original packer, or the final distributor, for example, need not be changed every time the article changes ownership."

### SWISS CHEESE—"SANDWICH CUTS"

If "Sandwich Cuts" of Swiss cheese, packed in shipping cases, are never sold by retailer to consumer intact, but are unwrapped by the retailer and the cheese sold by the slice to the consumer, the individual cuts need not be labeled.

TC-157—March 7, 1940

Correspondent inquires in regard to the labeling provisions of the Act as they apply to "Sandwich cuts" of Swiss cheese varying in size and weighing from one to eight pounds each.

"You advise that these cuts are wrapped in cellophane and packed in a carton or shipping case holding about 35 pounds, and that the outside of the carton or shipping case is marked with the net weight of the entire contents. You further state that your name does not appear on the individual pieces of Swiss cuts; in other words, they are not labeled. You also state that you ship these cartons of cheese to distributors in several States and they in turn sell to retail establishments, weighing each piece or cut as they sell it, and that the retailer slices or cuts the cheese and resells to consumers. You ask whether you are required to weigh each piece or if it is sufficient to weigh each carton and mark the net weight on the outside of the carton as described.

"If we are correct in our understanding that the cellophane-wrapped 'Sandwich cuts' are (1) not whole cheeses but merely cuts

varying in weight, (2) are never sold by the retailer to the consumer intact but are unwrapped by the retailer and the cheese sold by the slice to the consumer, (3) are weighed in the presence of the consumer and sold by weight, it is our present opinion that it is not necessary for the cellophane-wrapped cuts of cheese to be labeled. The labeling required by the Act for food packages should, however, under these circumstances, appear on the carton in which these individual 'Sandwich cuts' are shipped to the distributor. If it later develops that this may be an incorrect interpretation of the labeling requirements applicable in the circumstances, that will, of course, revise our opinion, and notice to that effect will be given.

"If in any case the cellophane-wrapped sandwich cut is sold intact to a consumer, it would then constitute a retail package and be required to bear the mandatory label information; that is, the name and place of business of the manufacturer, packer, or distributor, the net weight, and the common or usual name of the article, that is, 'Swiss Cheese.'"

### "HOME MADE" BRAND

If the particular food to which "Home Made" is applied is one which the public might still expect to be made in the home kitchen for commercial use, the term, even qualified by "brand," should not be used if the product is made in a commercial factory.

TC-158—March 7, 1940

"You inquire as to the propriety of the phrase 'Home Made' to designate a brand.

If the particular food to which this term is applied is one which the public might still expect to be made in the home kitchen for



commercial sale, which might well be the case with orange marmalade, we think the term, even qualified by the word 'brand,' should not be used if the product is made in ordinary commercial factories. On the other hand, if it is applied to some product which is generally understood to be no

longer made in the home for commercial distribution, the term 'Home Made' might possibly be used without a misleading implication, provided the particular product was made under conditions simulating those in the home as closely as possible with respect to the formulas and materials used."

### "EGGS"—BEVERAGE LABELING

"Eggs" may be used in the ingredient list on the label of a beverage when frozen whole eggs are used.

TC-159—March 14, 1940

"While the Administration's letter to the trade regarding the method of declaring eggs in bakery product would not be applicable to beverages, we see no objection to the use of the word 'eggs' in the ingredient list on the label of a beverage when frozen whole eggs are used in its preparation un-

less the plural of the word gives the impression of more egg content than is the case. In any event, there would be no objection to the term 'egg.' However, if present only in inconsequential proportions, it will be necessary to declare the percentage of egg or otherwise indicate the amount present."

### DEVICES, DANGEROUS DEVICES, SURGICAL INSTRUMENTS

The letter contains a discussion of the Administration's views on the labeling requirements of the usual surgical instruments, which are regarded as devices under Section 201(h).

TC-160—March 14, 1940

Visitor at interview submitted a list of questions, the answers to which were furnished in a letter.

Are the usual surgical instruments used by surgeons, such as knives, scissors, forceps, saws, mallets, chisels, needles, drills, nails, and screwdrivers, embraced within the definition of "device" contained in Section 201(h) of the Federal Food, Drug, and Cosmetic Act? Yes.

Must each surgical instrument or other therapeutic device be packed in an "immediate container" or retail package? No. Section 502(b) requires that devices bear certain labeling "if in package form." It does not compel the enclosure of a device in an immediate container.

If surgical instruments and other therapeutic devices are sold not contained in an "immediate container" or retail package, must they be labeled? Not necessarily. However, in some instances it is entirely possible that under the requirements of Section 502(f) some form of labeling will have to be attached conveying adequate directions for use and appropriate warnings against misuse. For example, a sun-ray lamp intended for use by the general public would unquestionably be required to bear a label containing directions and warnings against the danger of over-exposure. If the methods of use and essential precautions

were not necessarily known to the professional user, such directions and warnings would be required even if sale were restricted to such users.

May therapeutic devices, particularly surgical instruments, be labeled by attaching to the device, by means of a string, a tag on which is printed the information required by the Federal Food, Drug, and Cosmetic Act? Yes.

Must the name of the device be stated on the label? No.

May the manufacturer or the distributor of the device at his option print on the label of the device its common or usual name? Yes.

Must the name and place of business of the manufacturer, packer, or distributor of a therapeutic device be stated on the label? If there is a label, yes.

Must an accurate statement of the quantity of contents by net weight, measure, or numerical count of the device appear on the label of surgical devices sold in "immediate containers" or retail packages? Yes, unless exempted under paragraph (m) of the regulation under Section 502(b). Ordinarily a statement of numerical count would satisfy the requirements.

In case of a sale of surgical instruments and other therapeutic devices to a physician, surgeon, nurse, or hospital may such purchaser be considered an "ordinary indi-



vidual" as that term is used in Regulation (b)(1) under Section 502(f)? Yes, if the device is of a type obviously designed for use by and its distribution restricted to nurses, physicians, hospitals, or dentists who would necessarily be familiar with the uses of the articles, directions for use would not be required.

Must the label on therapeutic devices sold to physicians and nurses contain the warning required by Section 502(f)(2) "against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users?" Yes, unless the devices are of a type exclusively sold to physicians and nurses, and the proper methods of use and the proper precautions are obviously well known to these users.

Can one general label be used on all therapeutic devices sold to physicians and nurses reading substantially as follows: "This article is sold for use by physicians and nurses and not for self use," followed by the name and address of the manufacturer, packer, or distributor? Yes. In unusual instances adequate directions and precautionary statements should also be attached. This would most frequently involve new devices when the professional customers have not previously become aware of the precautions necessary.

Are there any labeling requirements with reference to the wholesale or shipping container in which therapeutic devices are shipped by manufacturers to dealers and by dealers to ultimate purchasers? No, except that any labeling that does appear shall be free from false or misleading implications. \* \* \*

#### GELATIN DESSERT PACKAGES—"SLACK-FILL"

Notwithstanding that the amount of powder in a gelatin dessert package may bear no set relation to the amount of final dessert obtained by following the directions, since the housewife buys the product with the idea of how many people the package will serve, the packages used should be redesigned so as to avoid slack-filling and consequent deception.

TC-161—March 14, 1940

Correspondent states that although the packages of flavored gelatin dessert under discussion are slack-filled, this fact makes no difference to the consumer when the amount of powder in the package bears no set relation to the amount of final dessert obtained by following the directions, since the housewife buys the product with the idea of how many people the package will serve.

"We \* \* \* fully appreciated the point you raised in regard to packages of this type being designed to furnish material for standard amounts of finished dessert. However, as we should have pointed out in our reply, we cannot share your conclusion that the practice of packaging quantities to bring about this result eliminates the possibility of deception under Section 403(d), nor do

we think the requirement resulting from Section 403(d) that the package be full is at all incompatible with the practice of packing so as to produce the same volume of final dessert.

"We fully appreciate that there are engineering problems confronting manufacturers in redesigning certain types of packages so that they will no longer be subject to question from the standpoint of deceptiveness. Several industries involved in similar situations have already redesigned packages to comply with the deceptive package provisions of the law and others are in the process of making changes, and we are looking to gelatin dessert packers for prompt changes in packaging practices where slack filling is involved, no matter whose particular package and packaging machinery are involved."

#### ISOPROPYL ALCOHOL IN COAL-TAR COLOR MIXTURE

Isopropyl alcohol is not a suitable ingredient in a coal-tar mixture for food use.

TC-162—March 14, 1940

Regarding an application for certification of a liquid food coloring mixture, in which isopropyl alcohol has been used as an in-

gredient, to the extent of about 3.3 per cent.

"While pharmacological investigations have not yet definitely established the toxicity of isopropyl alcohol, it is felt that



its properties are not sufficiently well-known to permit our regarding it as suitable for use in colors which are to be certified.

"We therefore cannot accept your application for certification of the mixture. \* \* \*"

### X-RAY MACHINES

The unrestricted distribution of X-ray machines would be in violation of Section 502(j). The labeling of such machines should include warnings and adequate directions for use.

TC-163—March 14, 1940

"Since it is well recognized that an X-ray machine is capable of producing serious injury unless handled by a person thoroughly familiar with its operation, we would regard the unrestricted distribution of any such device as in violation of Section 502(j) of the Act.

"We have given no consideration to the type of warnings which might be required in order to comply with Section 502(f) since such warnings would obviously depend upon the construction and power of the particular X-ray device sold."

"\* \* \* Section 502(f)(1) definitely requires that adequate directions for use be a part of the labeling of a drug or device. The proviso in that section authorizes the Secretary to promulgate regulations ex-

empting such drug or device from such requirement where the public health will be protected by the observance of the regulations. A manufacturer taking advantage of this proviso should therefore follow the regulations exactly in drawing up his labeling.

"The literature referred to \* \* \* as accompanying the X-ray equipment should, in the opinion of this Administration, reiterate this warning and provide in detail information which will enable the operator to avoid too frequent, too prolonged, or too close exposure to the X-rays in order to avoid injury. It appears that such directions will have to be specific for the various size and types of machines sold in order to provide the necessary information to insure safety for both the operator and the patient."

### STROPHANTHUS

Strophanthus is a potentially dangerous drug. Letter contains discussion of the declaration of the strophanthin content.

TC-164—March 14, 1940

"You may wish to consider the inadvisability of using tincture strophanthus, since this drug is so variable when used by mouth and frequently exhibits adverse effects on the heart and blood circulatory apparatus. Refer to Section 502(f)(1) and (2) as well as Section 502(j). \* \* \*"

"Strophanthus as you state is standardized by means of its equivalency to ouabain. Strophanthin is defined in the Pharmacopoeia as 'a glucose or a mixture of glucosides' which possesses 'a potency equivalent to the activity of not less than 40 per

cent and not more than 60 per cent of ouabain.' This is based upon the fact that the potency of a given weight of ouabain is equivalent to that of twice that weight of strophanthin. It follows that having determined the potency of strophanthus in terms of ouabain, the amount of strophanthin to be declared may be calculated by multiplying the amount of ouabain by 2. Unless or until changes are made in the Pharmacopoeial definition and procedure, the Administration will consider a declaration of strophanthin on this basis as meeting the requirements of the statute."

### DANGEROUS DRUGS

The responsibility for determining which drugs are dangerous is that of their manufacturer and distributor.

TC-165 (See TC-326 and 361)—

March 14, 1940

"Section 502(j) of the Act prohibits the sale of drugs which may be dangerous to health. There are drugs which are dangerous if used without adequate or continuous

scientific direction. As illustrations of this class the Administration has mentioned sulfanilamide, aminopyrine, cinchophen, and neocinchophen. It has not undertaken to make a complete list of drugs falling in this category. Obviously such dangerous drugs



should not be indiscriminately distributed whether or not the labelings carry directions for use."

"The responsibility for determining whether or not any particular drug is 'dangerous,' as that term is used in Section 502(j) must rest upon the manufacturer and distributor. The Administration, while it

has given a few examples of what it regards as dangerous drugs, when they are indiscriminately distributed, has not undertaken to bear the burden of determining in all instances whether or not drugs are too dangerous for use except under professional guidance. The Administration has no intention of assuming this burden."

#### MACARONI PRODUCTS—NOODLES—INGREDIENT DECLARATION

Declaration of ingredients in macaroni and egg noodles is not being required for products which conform to the advisory standards therefor under 1906 statute (S. R. A., F.D. No. 2), since new standards are under consideration.

TC-166—March 14, 1940

"Section 403(i)(2) of the Act requires, in the case of foods prepared from two or more ingredients, that they bear a label declaration of the ingredients by their common or usual names. However, in the case of macaroni and egg noodles which conform to the advisory standards for these products promulgated in the enforcement of the Food and Drugs Act of 1906, \* \* \* (S. R. A., F. D. No. 2), we are not disposed

to require the declaration of ingredients inasmuch as new standards for these products are now under consideration. In the event that standards are promulgated for macaroni products, including noodles, the regulations may require declaration of some of the ingredients. Announcements issued in connection with the formulation of standards for these products will appear in the Federal Register and will very likely receive publicity through trade channels."

#### ARTIFICIAL COLOR—"FOOD COLOR ADDED"

The term "Food Color Added" is inappropriate to indicate the presence of artificial color.

TC-167—March 14, 1940

Correspondent asks whether the term "Food Color Added" is sufficient to indicate the presence of artificial color.

"Section 403(k) of the Act bears specifically upon your inquiry regarding the

propriety of the words 'Food Color Added.' In our opinion they may be erroneously interpreted to mean the color is derived from food. The legend should be changed to 'Artificial Color Added,' 'Color Added,' or an equally informative statement. \* \* \*"

#### BAKERY PRODUCTS—UNWRAPPED; CAKE FRUIT FILLERS; NUTS

Unwrapped pie, cake, and bread require no labeling. If any kind of label is applied, the label must contain the required information.

TC-168—March 14, 1940

"With reference to unwrapped pies and cakes, it is not held that the Act requires products not normally sold in wrappers or containers to be so enclosed. Unwrapped pies and cakes will not be held as requiring the name and address of the manufacturer or distributor, the net weight, or the ingredients of the article. If wrapped, the label statements prescribed by the Act are required. This is also true where, as in the case of a loaf of bread, a paper label or sticker is applied to the loaf, even though the loaf is otherwise unwrapped. If the manufacturer or distributor applies any kind of a label, it is obvious that the label must contain the required information.

"In the case of cakes, for instance, which contain between the layers a filling of

orange or pineapple, it would not be considered a sufficient identification of the fruit merely to label it as containing fruit filler. The actual nature of the fruit, whether orange, pineapple, or what not, should be indicated since these ingredients certainly contribute to the characteristics of the finished product.

"The same is true in the case of a cake in which various types of nuts, like walnuts, pecans, almonds or peanuts, have been incorporated. If only one type of nut is used, the name of that nut should be specifically declared. Where the amount of a particular nut present is such as to warrant its name being applied to the cake, such as 'walnut cake,' the incorporation of the name



of the nut in the name of the article would be a sufficient declaration of that ingredient. Where the baker produces a type of baked product containing mixed nuts, the proportion of the mixture varying from time to time but the same types of nuts

being present in varying quantities, it would not be expected that separate labels should be kept on hand. The Act requires a qualitative and not a quantitative declaration. \* \* \*

### CANNED PINTO BEANS—"BROWN BEAUTY BEANS"

Letter suggests that labels of pinto beans, called in trade by familiar name "Brown Beauty Beans," display the word "pinto."

TC-169—March 14, 1940

Correspondent packs a type of pinto beans under the name "Brown Beauty Beans" and inquires whether the Act will require the label to state that these beans are pinto beans or whether they can continue to be called merely "Brown Beauty Beans," a term with which his trade is familiar.

"In the absence of any standard as yet under the new \* \* \* Act for canned beans of this type we must seek the answer to your question in Section 403(i) of the Act, which requires the label to bear the common or usual name of the food if any there be. Whether or not the courts will interpret this to mean that the common or usual name is merely 'beans' or is in this case

'pinto beans' is perhaps a matter of speculation. We, therefore, cannot say definitely that the word 'pinto' must appear, but certainly in the interest of more informative labeling and in anticipation of the possibility that 'pinto beans' may be held to be the common or usual name, we suggest that your new labels display the word 'pinto.' This, of course, does not preclude your continuing to use the term 'Brown Beauty Beans' on the label provided the words 'Brown Beauty' do not mislead in any way as to the variety or type of the bean. You might label the product 'Brown Beauty Beans,' this term followed by a conspicuous statement, in parenthesis if desired, 'Pinto Beans.'"

### COSMETICS—COSMETIC INGREDIENTS—TOLERANCES FOR LEAD AND ARSENIC CONTENT

Until such time as more evidence than is now available has been developed on the effects of the external application of lead and arsenic, the Administration must refrain from setting up definite tolerances for cosmetics and cosmetic ingredients.

TC-170—(Amplifies TC-27)—  
March 14, 1940

Correspondent asks whether the Administration, in enforcing the cosmetic provisions of the Food, Drug, and Cosmetic Act, can set a limit for cosmetic ingredients of 50 parts or more of lead and arsenic per million, provided they are used in such concentration that the final product contains less than 20 parts lead and 2 parts arsenic.

"The provision of the Act applicable to poisonous ingredients in cosmetics is Section 601(a) which deems a cosmetic to be adulterated 'if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual'. The term 'cosmetic' as defined in Section 201(i) covers not only the finished cosmetic but also articles intended for use as components thereof.

"The Administration has been importuned to set up general tolerances for impurities like arsenic and lead in finished cosmetics but has been obliged to refuse to do so because of the lack of data so far available upon the effect of such impurities when applied externally as in the case of cosmetics. The only exception has been in the case of coal-tar colors where the tolerances you have mentioned, applicable to certified colors, have been established by regulation in recognition of the fact that the finished cosmetics will contain comparatively small proportions of the dyes.

"Administratively we recognize that there is less hazard involved in the presence of a certain amount of lead, for example, in a cosmetic constituent, than if the same amount were present in the finished article. The degree of dilution, however, as well as other factors like the use to which the finished cosmetic is to be put may play an important part in the determination as to



whether or not the constituent is of suitable purity for use in cosmetics. Until such time as more evidence than is now available has been developed on the effects of the external application of lead and arsenic the Administration must refrain from setting up definite tolerances for cosmetics and cosmetic ingredients.

"The Administration up to this time has not held any particular cosmetic ingredient to be outlawed because of the presence of lead and arsenic. It counsels consistently that manufacturers use every possible precaution to keep the amount of all toxic impurities down to the lowest practicable minimum."

### FLAVORING COMPOUNDS—COAL-TAR COLORS

Flavoring compounds containing coal-tar colors, if intended to color as well as flavor food to which added, require certification.

TC-171(See also TC-219)—  
March 14, 1940

Correspondent states his opinion that there is no justification for the necessity of having small batches of food coloring compounds re-certified when certification is not necessary in the case of flavoring compounds containing the same coal-tar colors.

"Section 406(b) of the Federal Food, Drug, and Cosmetic Act states that 'The Secretary shall promulgate regulations providing for \* \* \* the certification of batches of such colors with or without harmless

diluents.' The enforcement of this section of the law is of course mandatory.

"Comparable requirements were not imposed upon flavoring compounds when the certified color is present simply to color the flavoring mixture. If, however, the color is present in sufficient concentration so that the product is intended to color as well as flavor the food to which the mixture is added, the mixture would then in our opinion be a diluted color and would need to be certified."

### BUTTER—USE OF NEUTRALIZER IN CREAM

There is no intention to regard a neutralizer used in cream for churning as a chemical preservative under Section 403(k). This is not to be construed as constituting approval of the use of a neutralizer in cream.

TC-172—March 14, 1940

"It is not our intention at this time to regard a neutralizer used in cream for churning as a chemical preservative under Section 403(k) of the Act, which requires

label declaration of any chemical preservative. This statement of course is not to be construed as constituting approval of the use of a neutralizer in cream."

### ARTIFICIAL FLAVORS

The label of a food which is artificially flavored must specifically state such fact. There is no objection, however, to adding a statement of the constituents of the artificial flavoring.

TC-173—March 14, 1940

"Under date of \* \* \* in reply to an inquiry we advised you in part that if the flavoring of an imitation grape soda is, in whole or in part, synthetic, the word 'Flavoring' should be changed to 'Artificial Flavoring' or 'Artificial Flavor' or each constituent of such flavor should be named on the label as provided in Section 403(k) of the Act.

"Further consideration of this section of the new Food, Drug, and Cosmetic Act has led to the conclusion that a correct inter-

pretation of the language 'unless it bears labeling stating that fact' will make it mandatory that the presence of the artificial grape flavor in your product be declared by the words 'Artificial Flavoring' or 'Artificial Flavor' without the option of declaring each constituent of the flavor in lieu of the above declaration. There is, of course, no objection to stating each constituent of such flavor in addition to the legend 'Artificial Flavoring' or 'Artificial Flavor.'



**EXEMPTIONS FOR PRESCRIPTIONS—PHYSICIANS**

A physician who does his own dispensing may avail himself of the exemption provided by Section 503(b). Drugs shipped to a physician should be labeled in compliance with law.

TC-174—March 14, 1940

Correspondent's letter concerns the labeling of products which are marketed in bottles designed for the dispensing doctor.

"Section 503(b) of the Act provides that a drug dispensed on a written prescription signed by a physician, dentist, or veterinarian may, under certain conditions, be exempt from the requirements of Section 502 (b) and (e), and, under certain circumstances, from the requirements of Section 502(d). It is our opinion that a physician who does his own dispensing is also acting in the capacity of a pharmacist and may avail himself of the exemption provided by Section 503(b) if he fulfils all the requirements of this section. The drugs as sent to the physician must, of course, comply with all sections of the Act."

"We realize that there are circumstances in which the public interest would perhaps not be jeopardized by continuing the practice of furnishing drugs to physicians with blank direction labels. I am sure you will appreciate that such a practice would easily be subject to serious abuse in a way which would circumvent the plain intent of the law. Congress omitted any exemption for

goods shipped under the conditions you mention presumably because of this fact.

"Some manufacturers have adopted the practice of using a directions label with a perforated stub which carries all the information required by the law. It seems to us that this device meets the essential requirements of the Act, avoids the likelihood of confusion with regard to the identity and composition of the article even when the bottles are removed from the carton, and yet enables the physician who wishes to use the preparation as a prescription to do so with the least inconvenience."

"At the time of the interview we pointed out that the applicability of Section 503 (b) of the Act was dependent upon certain conditions prescribed in clause (2) of this section of the Act, and pointed out that the mandatory information prescribed in clause (2) should be placed on the residual portion of the label attached to the package given to the patient. The blank portion of the label should preferably provide space for the number and date of the prescription and for the address as well as the name of the physician.\* \* \*"

---

**TOMATO PRODUCTS—ARTIFICIAL COLOR**

The standards promulgated for tomato puree, paste, catsup, and juice do not recognize artificial color as an ingredient. The addition of artificial color would constitute a violation.

TC-175—March 14, 1940

Correspondent inquires about the status of artificial color in tomato products under the Food, Drug, and Cosmetic Act.

"Under the authority contained in Section 401 of the Act, definitions and standards for various tomato products, including puree, paste, catsup, and tomato juice, have been promulgated effective January 1, 1940. The law provides that food products for which definitions and standards have been prescribed by regulation shall conform with such definitions and standards.

"None of the standards promulgated for the indicated products recognizes artificial color as an ingredient of the article. It

follows, therefore, that after the effective date of the standards artificial color will no longer be permissible in these tomato products. \* \* \* Section 402 of the Act, which took effect on June 25, 1939, defines a food product as adulterated, among other things, 'if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to \* \* \* make it appear better or of greater value than it is.' It is our opinion that under this section of the Act artificial color in tomato products would of necessity be classed as an adulteration."

---



**CHOCOLATE FLAVORED WITH VANILLIN**

When added to a food, vanillin should be declared on the label as an artificial flavoring in order to insure compliance with Section 403(k). Forms of declaration are suggested.

TC-176—March 14, 1940

"In conformity with the appointment referred to \* \* \* your committee visited the Administration \* \* \* and presented facts and arguments in support of your request that the Administration reconsider its ruling that, when added to chocolate, vanillin must be declared on the label as artificial flavor. You pointed out that vanillin is not added to chocolate for the purpose of developing a flavor simulating that of vanilla, but has an effect more like that of salt when added to foods. You feel that it alters and accentuates the flavor of chocolate or in other words removes the flatness of chocolate containing no vanillin. You pointed out that it would not be practicable to add vanillin in an amount sufficient to simulate the flavor of vanilla since before that stage was reached the product would have a bitter taste.

"We have given very thorough consideration to the committee's representations. It is my understanding there is no contention on your part that vanillin is not an artificial flavoring but your point is that it does not produce a flavor suggestive of any particular well defined thing like vanilla, for example. It does seem clear, however, that you are in agreement that the addition of vanillin to chocolate alters its flavor or

taste characteristics. The conclusion seems inescapable to us, therefore, that it is a flavoring, and since it is artificial the language of Section 403(k), in our opinion, requires that fact to be made known on the label. We cannot give the consent of our own judgment to a conclusion that simply designating the added ingredient on the label as 'vanillin' would insure purchasers understanding that the added vanillin is artificial. The term 'vanillin' alone is very similar to and suggestive of vanilla and, in our opinion, it is almost inevitable that the unqualified term 'vanillin' will suggest to some consumers a genuine rather than an artificial flavoring.

"Under these circumstances we can only reaffirm the informal opinion which we have previously expressed, that, when added to a food, vanillin should be declared on the label as an artificial flavoring in order to insure compliance with Section 403(k). It is, of course, optional with the manufacturer or shipper whether he restricts the legend to the words 'artificial flavor' or 'artificially flavored' or goes further and states 'artificially flavored with vanillin.' We would be disposed to regard the legend 'flavored with synthetic vanillin' as a satisfactory equivalent to 'artificial flavor.'"

**FLAVORS CONTAINING VANILLIN OR ETHYL VANILLIN**

Flavors containing vanillin or ethyl vanillin, which are not imitations, should be labeled to show they contain artificial vanillin or ethyl vanillin. In the case of imitation vanilla flavor containing vanillin or ethyl vanillin, the name "Imitation Vanilla Flavor" sufficiently indicates that the vanillin or ethyl vanillin is artificial.

TC-177—March 14, 1940

"Flavors containing vanillin or ethyl vanillin, which are not imitations, should be labeled to show that they contain vanillin or ethyl vanillin, as the case may be, and to show that the vanillin or ethyl vanillin is artificial.

"In the case of imitation vanilla flavor containing vanillin or ethyl vanillin, it will

suffice, in our opinion, to declare the presence of vanillin or ethyl vanillin, as the case may be, without indicating that the vanillin or ethyl vanillin is artificial. We believe that the name 'Imitation Vanilla Flavor' sufficiently indicates that the vanillin or ethyl vanillin is artificial.\* \* \*

**BUTTER—LABELING**

Since pound cartons of butter are frequently broken in a retail store and sold in quarter-pound units, it is suggested that the quarter-pound units be labeled. The letter discusses the use of grading certificates as part of the labeling.

TC-178—March 14, 1940

Correspondent inquires whether it is necessary under the Act to have the wrapper

printed on each quarter-pound stick of butter with the same information that is embodied on the one-pound carton when but-



ter is wrapped four quarters to a one-pound package.

"If it could be assured that in all cases the one-pound carton would be the unit of retail sale, it would not be necessary to repeat the required label information on each quarter-pound print. However, we know it is quite frequently the practice to break a pound carton in the retail store and sell a quarter-pound stick as a unit, and in such cases the one-quarter-pound stick would become the package which requires the mandatory label information. In order to be assured of compliance with the Act in any case, we suggest that the one-quarter-pound stick wraps be labeled."

Correspondent refers to the use of certificates setting forth the score of a particular

butter in connection with the labeling of butter, these certificates being used under an arrangement with the Bureau of Agricultural Economics. (Agricultural Marketing Service).

"Such certificates which appear as a part of the labeling of butter are, of course, subject to the same general labeling requirements applicable to any other statements or representations appearing on the label. They must not be false or misleading in any particular. We have not found fault with such certificates when they accurately reflected the quality or score of the butter at the time of grading and if, as is the case, the certificates clearly indicate that the stated grade is that found at the time of grading, the date of grading being also given."

### FROZEN SWORDFISH

Pending final decision, importations of frozen swordfish in 50-100 lb. pieces will be considered as bulk shipments.

TC-179—March 15, 1940

"Large pieces in the round, boned or fillet form, weighing from fifty to one hundred pounds, frequently are placed in burlap or other wrappers to promote cleanliness and to facilitate handling. Determination has not been reached whether these constitute

food in package form. Pending final decision, action will not be taken on such bulk units solely on the ground that they are not labeled with the name and place of business of the manufacturer, packer, or distributor, or with a statement of the quantity of contents."

### LEMON, ORANGE, AND VANILLA NON-ALCOHOLIC FLAVORS

The exception with respect to the listing of ingredients on lemon, orange, and vanilla extracts would not apply to lemon, orange, and vanilla flavors containing the required flavoring ingredients under the old standards but having a non-alcoholic base.

TC-180—March 15, 1940

Correspondent asks whether the exception with respect to listing of ingredients on lemon, orange, and vanilla extracts would apply to lemon, orange, and vanilla flavors containing the required flavoring ingredients under the old standards but having a non-alcoholic base.

"The Secretarial exemption which you have in mind \* \* \* specifically refers to

'lemon extract; orange extract; vanilla extract,' with no mention of non-alcoholic flavors. It is our conclusion that the temporary exemption from listing ingredients does not extend to the corresponding non-alcoholic standard flavors; consequently labels for non-alcoholic lemon, orange, vanilla, and other flavors should declare the ingredients in accordance with Section 403 (i) (2)."

### LABELING OF DRUGS

In some instances, as in the case of warnings of the danger of the unsupervised administration of aminopyrine, directions and warnings should appear prominently upon the principal panels of the bottle label and outside wrapper or container.

Directions for use and warnings should appear together.

TC-181—March 15, 1940

"\* \* \* The information required by Section 502 (f) relating to directions and warnings, is required by the Act to appear on

the labeling. Section 502 (c), however, requires that such information appear on the labeling with such conspicuousness and in such terms as to render it likely to be read



and understood by the ordinary individual. Section 502(f)(2) requires that these warnings be in such manner and form as are necessary for the protection of the public health.

"It is obvious that in some instances the purpose of the Act can be effected only if such directions or warnings appear prominently upon the principal panels of the bottle

label and outside wrapper or container. In this class would fall warnings of the danger of the unsupervised administration of aminopyrine.\* \* \*

"It has been our opinion that the warnings should appear in connection with the directions for use; where such directions appear upon the label the warning should also appear there.\* \* \*"

### COAL-TAR COLOR CERTIFICATION PROCEDURE

A dry color manufacturer may dilute the color at the order of an interstate customer and, in the name of the customer, submit sample of mixture for certification before bulk shipment of mixture is made.

TC-182—March 15, 1940

Correspondent asks two questions based on hypothetical cases:

(1) A coal-tar color manufacturer sells a certified dry color to an interstate customer, who wishes to use it for making liquid color. The manufacturer of the dry color does the mixing and ships the diluted color in bulk to the customer, who then submits a sample for certification and repacks the color for sale in one-ounce bottles. *Question:* Is the interstate shipment of the bulk color before certification a violation of the Act?

(2) The procedure is the same as in (1) up to the shipment of the bulk color. The dry color manufacturer now submits a sample of the liquid color and obtains a certificate for this color in the name of the

customer. He then ships the certified liquid color in bulk to the customer, who repacks it for sale in one-ounce bottles.

"With respect to situation No. 1, it is our opinion that a shipment of the liquid color in interstate commerce prior to its being certified would violate Section 402 (c) of the Act.

"In the second case, assuming that your company is acting entirely as the agent of a manufacturer, we see no reason why you could not mix the product and send in a sample for certification in the name of the final manufacturer. After such certification had been granted, the shipment of the barrel of finished color could take place, provided that the requirements of the regulations under Section 405 of the Act were met."

### DRUGS—PHYSICIANS

Interstate shipment of drugs by a doctor to a patient constitutes interstate commerce. Interstate transportation of medicines by patients to their homes is not interstate commerce.

TC-183—March 15, 1940

"With reference to medicines given to your patients at your hospital and transported by them to their homes in some other states for use by themselves, it is our opinion that such a transaction is not interstate commerce as that term is defined in

Section 201 (b) of the Act. We are still of the opinion, however, that the shipment of drugs by you to patients in other states, whether by mail, express, messenger, or otherwise, is interstate commerce, and that products so shipped are required by the statute to comply with its terms."

### TOMATO PUREE—PRODUCT NOT CONFORMING TO STANDARD LABELED "IMITATION"

Product having the consistency and general appearance of tomato puree, but not conforming to standard, is misbranded. Administration has serious doubt as to the legality of the product, but if it were legal under any form of labeling it would have to be labeling which designates the product as "Imitation Tomato Puree" in conformity with Section 403(c).

TC-184—March 15, 1940

Correspondent submitted a sketch for a proposed lithographed tin for a product called "\* \* \* Sauce" which apparently con-

sists of tomato paste diluted with water, and containing paprika, salt, spices, and artificial color.



"Although the degree of dilution is not indicated, we assume that this product would have the consistency and general appearance of tomato puree." (Subsequent correspondence indicated that product, as diluted will have a salt-free tomato solids content of 6.25 per cent.) "As you know, a definition and standard of identity for tomato puree promulgated under the new Food, Drug, and Cosmetic Act is now in effect. This product, in our opinion, will therefore purport to be tomato puree, although there is no recognition in the standard of the presence of artificial color or of the presence of diluted tomato paste.

"Section 403 (g) of the Act \* \* \* deems a food to be misbranded if it purports to be

or is represented as a food for which a definition and standard of identity has been prescribed, unless it conforms to such definition and standard. This product does not conform with the definition and standard of identity for tomato puree and is therefore misbranded. In view of the silence of the new Act in regard to the status of a food failing to meet the definition and standard of the food it purports to be, we have serious doubt as to the legality of this product, but we believe that if it were legal under any form of labeling it would have to be labeling which designates the product as 'Imitation Tomato Puree' in conformity with Section 403 (c).\* \* \*

### PEANUT BUTTER—ADDITION OF GLYCERIN

The addition of glycerin to peanut butter would not be permissible if it resulted in the concealment of inferiority or made the article appear better than it is. If glycerin can be added without involving adulteration, the label must carry a conspicuous declaration.

TC-185—March 15, 1940

Correspondent discusses the question of the addition of 1½ to 2 per cent of glycerin to peanut butter as an aid in preventing oil separation.

"Under the terms of the Federal Food, Drug, and Cosmetic Act, such addition would not be permissible if it resulted in the concealment of damage or inferiority or made the article appear to be better or of greater value than it is. If glycerin can be added to peanut butter without involving adulteration, then the Act would require the

addition of glycerin to be conspicuously set forth on the label. While no standard of identity or quality has as yet been formulated under the new Act, the term 'peanut butter' is generally understood by the consuming public to mean a product consisting solely of ground roasted peanuts, with or without a small quantity of added salt. Therefore, the addition of glycerin would change the identity of the peanut butter and necessitate the label statement indicated above."

### SULFANILAMIDE

The letter sets forth a warning statement with respect to sulfanilamide which some manufacturers have adopted.

TC-186—March 15, 1940

"A warning which has been adopted by some manufacturers to appear on the display panel or panels of the label for this drug is essentially as follows:

*"Sulfanilamide*

*"Warning: This is a dangerous drug which may cause serious or fatal injury,*

*unless consumed under adequate and continuous medical supervision.*

*"Caution: Therefore it is to be used only by or on the prescription of a physician; and never otherwise."*

### DRUGS—DIAGNOSTIC PREPARATIONS

Diagnostic preparations described in the back of the National Formulary come within the definition of drug in Section 201 (g).

TC-187—March 15, 1940

Correspondent inquires whether the diagnostic preparations described in the back of the National Formulary are subject to the provisions of the Act and how they should be labeled.

"\* \* \* You will note that the definition of the term 'drug' which appears in Section 201 (g) of the Act includes articles intended for use in the diagnosis of disease in man or other animals.



"Section 502 of the Act relates to the labeling of drug products. You will note that the label will be required to bear the name and place of business of the manufac-

turer, packer, or distributor, an accurate statement of the quantity of contents, and the common or usual name of the reagent."

#### DIGITALIS PREPARATION—POTENCY DECLARATION

The potency declaration of a digitalis preparation may be in terms of cat units, but this must not be in substitution for the requirement for the statement of the quantity of digitalis present.

TC-188—March 15, 1940

"There is no objection to the statement of the activity of a digitalis preparation in terms of cat units. This, however, must be in addition to, and not in substitution for, the requirement of the Act for the statement of the quantity of digitalis present. As you no doubt know, digitalis powder, which is the form in which this drug is ordinarily sold, is a standardized prepara-

tion, overstrength material being diluted with extracted digitalis marc. If such a drug is used in the manufacture of tablets, there would be no necessity for varying the grainage with different batches of tablets. It should be noted also that declaring the potency in cat units will not obviate the necessity of compliance with the Pharmacopoeial standard for digitalis. The official assay is based upon the effect on frogs."

#### DRUG—LIST OF ACTIVE INGREDIENTS

The list of active ingredients on the label of a drug product should represent those present in the finished preparation.

TC-189—March 15, 1940

Correspondent states that a preparation for which a new drug application has been submitted contains sulfur, calcium, cayenne pepper, and Epsom salt.

"The labeling which you submit lists sulfur, Epsom salt, cayenne pepper, lime, and water as ingredients. As stated above,

the method of preparation" (by long boiling) "would bring about chemical changes between these ingredients, and it is therefore incorrect to list them as you propose. You should determine what the active ingredients are in the finished preparation and list each of these by its common name as required by Section 502 (e)."

#### DRUGS—"ACTIVE INGREDIENT"—INERT INGREDIENTS

If ingredients which contribute nothing to the physiological effects of a drug are listed on the label, Section 201 (n) would require the label to bear a statement that such ingredients are inert.

The term "active ingredient," as used in Section 502 (e) (2), includes all ingredients which contribute to the physiological effect of the drug in which used.

TC-190—March 15, 1940

"Any particular ingredient which a manufacturer introduces into his preparation is obviously introduced for some purpose. He should be in a position to determine whether or not he introduces it for its physiological effect or merely as a vehicle, excipient, flavoring, coloring, etc.\* \* \*

"We are of the opinion that if any ingredients which contribute nothing to the physiological effects of the article are listed on the label, Section 201 (n) of the law would require that the fact that such ingredients are inert should be stated. The general rule to be followed is that the listing of the ingredients should be informative to the purchaser and should not deceive or mislead."

"\* \* \* we are of the opinion that as used in Section 502 (e) the active ingredients of

a drug are those which effect or assist in effecting the purpose for which the article is offered or which may produce some physiological effect in contradistinction from diluents, excipients, coloring matters, etc. In determining which of the ingredients in the preparation are active the manufacturer should consider the purpose for which the ingredient is used and the physiologic effect, if any, it may cause.

"In the case you cite you state that the anise, cedar, and juniper oils contained in the article yield, when burned, a soot which is deposited in the nose and throat and makes the smoke from the burning stramonium and saltpetre continue longer than it otherwise would. Under these circumstances it would seem that the oils are introduced for the purpose of increasing the



effectiveness of the other ingredients and are, therefore, 'active' under the circum-

stances. It is our opinion that the oils should be declared as active ingredients."

### DRUG NOMENCLATURE—TITLES

Titles of drugs are misleading if some, but not all, of the active ingredients are mentioned. Congress has prohibited any interference with the designations of official titles.

TC-191—March 15, 1940

Inquirer stated that some manufacturers wish to know how far they must go in listing the active ingredients of drugs in the titles. He mentioned several examples, illustrative of which is a product called "Tolu and Codeine," which contains such ingredients as chloroform and tartar emetic.

"He was told that while we cannot, of course, state what the courts will ultimately decide about matters of this kind, we are of the opinion that the titles are misleading if they refer to part but not all of the active ingredients.

"He mentioned 'Syrup of Hypophosphites.' He was told that we recognize that the active ingredients in this article are not adequately described by the term 'Hypo-

phosphites,' since that designation refers only to the acid with which the really important ingredients are combined, but that in the case of official products, Congress has prohibited any interference with the designations.

"He then asked about the declaration of 'Sanguinaria Syrup' as an ingredient in another preparation, pointing out that 'Sanguinaria Syrup' was official in N.F. IV but is not now official. I told him that I do not think the regulations permit the use of such terms as 'Sanguinaria Syrup,' for which there is no official standard, that I thought the active ingredients should list Sanguinaria and any other active constituent of the syrup.\* \* \*"

### "INTERSTATE COMMERCE"—"IMPORT"—"EXPORT"

The term "interstate commerce," as it occurs in Section 201 (b), is broad enough to cover both interstate commerce and commerce with foreign countries.

The terms "import" and "export," as used in Section 801, are not defined. They are presumably to be interpreted in the sense in which they are ordinarily used.

TC-192—March 15, 1940

"\* \* \* the definition of the term 'interstate commerce' as it occurs in Section 201 (b) of the Food, Drug, and Cosmetic Act is broad enough to cover both domestic interstate commerce and commerce between the United States and foreign countries.

"The Act contains no definition of the terms 'import' and 'export,' which are used in Section 801. These terms are presumably to be interpreted in the sense in which they are ordinarily used. Section 801 (d) refers to 'export,' 'foreign purchaser,' and

'country.' The states, the District of Columbia, Alaska, the Canal Zone, and any other territory to which this country's sovereignty extends can hardly be regarded as foreign countries or their inhabitants as foreigners.

"In our opinion, Section 801 (d) constitutes an exemption with respect to the sections of the law defining adulteration and misbranding with respect to goods shipped from the United States or any of its possessions to a country not subject to its authority."

### DRUGS—ADEQUATE DIRECTIONS FOR USE NOT POSSIBLE UNDER CERTAIN CIRCUMSTANCES

Preparation held to be a mixture of ingredients wholly without scientific reason for its compounding and distribution, even to physicians, since it will be impossible for them with safety to administer the mixture so that they may produce in their patients the therapeutic effects of all the ingredients without danger of overdosing with respect to some of the ingredients.

TC-193—March 15, 1940

"The amount of quinine and sulfanilamide contained in this tablet is far below the dose for each which has been definitely

established as required to produce the therapeutic effects for which these drugs are customarily used, if used on the basis of established scientific fact. Of course your



directions for use leave it to the physician to determine the number of tablets and the frequency with which they will be administered. However, the presence of significant doses of acetophenetidin and aspirin places a definite limit upon the number which may be taken with safety. While the amount of sulfanilamide in this preparation is, from a therapeutic standpoint, insignificant, it is far from insignificant from a standpoint of the untoward effects which may result from taking a drug containing this ingredient. \* \* \*

"In the opinion of this Administration, this preparation is a mixture of ingredients wholly without scientific reason for its compounding and distribution, even to physicians, since it will be impossible for them with safety to administer this mixture so that they may produce in their patients the therapeutic effects of all the ingredients

without danger of overdosing with respect to some of the ingredients.

"It is difficult to see how you can, under the requirements of Sections 201 (n) and 502 (f) (2), provide adequate directions for use for this preparation as required by Section 502 (f) (1). Its laxative effect should result from one or two doses and to avoid the danger of establishing the laxative habit you should in positive terms warn against repeated use. From the preparation's proper use as a laxative no significant tonic effect will be had, as frequently repeated doses over a period of time are required for such tonic effect. You should decide whether you wish to distribute a laxative or a tonic and then make appropriate changes both in the composition of your preparation and its labeling.\* \* \*

### "MARASCHINO CHERRIES"

The term "Maraschino Cherries" held to be the common name of a product theretofore regarded as not entitled to the unqualified name "Maraschino".

TC-194—March 15, 1940

A committee representing a trade association visited the Administration and made known its contention that the term "Maraschino Cherries" has attained a broader significance than that set forth in Food Inspection Decision 141 issued in 1912 under the Food and Drugs Act of 1906 and has come to mean to the consumer cherries which have been dyed red, impregnated with sugar and packed in a sugar sirup flavored with oil of bitter almonds or a similar flavor.

"Section 403 (i) of the Federal Food, Drug, and Cosmetic Act requires that the label of a food product for which no definition and standard of identity has been prescribed shall bear the common or usual name of the food, if any there be, and in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except that spices, flavorings, and colorings may be designated as spices, flavorings, and colorings without naming each. The question is whether the term 'Maraschino Cherries' can be regarded as a common or usual name within the meaning of this Act. The evidence you have submitted shows a widespread acceptance and usage of this term on the product described above. Uncontroverted evidence of similar import was submitted at the public hearing

held on April 17, 1939, for the purpose of receiving evidence preliminary to fixing and establishing a reasonable definition and standard of identity for canned cherries, although such evidence was not strictly relevant to the purpose of that hearing. The Administration has reached the conclusion that the term 'Maraschino Cherries' may be regarded as the common or usual name of the article in question and may therefore be used to designate it on labels affixed to the product shipped within the jurisdiction of the Food, Drug, and Cosmetic Act.

"This, of course, presupposes that the labeling will meet the other requirements of the Food, Drug, and Cosmetic Act, including a proper fill of container, accurate and conspicuous declaration of the quantity of the contents, the name and address of the manufacturer, packer, or distributor, and the declaration of artificial flavoring, coloring, and preservative if present. Since no consideration has been given to the establishment of a definition and standard for maraschino cherries under Section 401 of the Food, Drug, and Cosmetic Act, the requirement of Section 403 (i) (2) that the common or usual name of each ingredient other than artificial flavoring, coloring, and preservative be declared will apply to the naming of the packing medium."



**SOYBEAN FLOUR—ADDITION OF CAROTENE**

While carotene does serve as medium for the introduction of Vitamin A, it is a coloring matter, and its use in baked goods is likely to involve adulteration. If in any case it would be possible to introduce soybean flour colored with carotene into a food product without involving adulteration, it would be necessary to label the product as containing added soybean flour and as being artificially colored.

TC-195—March 15, 1940

Correspondent's letter discusses the possibility of manufacturing a soybean flour enriched with vitamin A through the addition of carotene, requests the Administration's view on a product of this type, and asks whether it is necessary for a baker to label his goods to which this substance is added "carotene and soy flour added."

"While carotene does serve as a medium for the introduction of Vitamin A into food, it is, of course, well known that it is a coloring matter. This immediately raises the fundamental question as to whether, because of the inevitable complications result-

ing from this fact, it is desirable to contemplate the addition of carotene to soybean flour. The yellow color imparted to baked goods through the use of your colored soy flour, a color which suggests an egg content, will almost inevitably endanger the legality of such finished food products. If in any case it would be possible to introduce soybean flour colored with carotene into a food product without involving adulteration, it would, in our opinion, be necessary to label the product as containing added soybean flour and as being artificially colored."

**DRUGS—NAMES OF "ACTIVE INGREDIENTS"**

The name of the "active ingredient" to appear on a label should be the name of the drug used, not the names of its various ingredients.

If names of individual fish liver oils which are ingredients of product are not known, no objection will be taken to the use of language which will state the fact that the active ingredient is a mixture of fish liver oils and the presence and amounts of vitamins contained.

TC-196 (See also TC-75)—  
March 15, 1940

"Your question deals with statements of composition which should appear upon the label of vitamin products.

"It is not our view that the 'active ingredients' dealt with in the statute refer to the various constituents of an ingredient used, as, for example, vitamins contained in a fish liver oil. If this meaning were attributed to the language of the statute, in the case of many medicinal compounds the result would be that the Act would require the numerous constituents of every non-official drug which might be regarded as active to be stated on the label. In many

instances, the identity of such constituents is not known. We do not believe that Congress intended to make this requirement. Manufacturers do, of course, ordinarily know the names of the ingredients which they add to make their products. If, as a matter of fact, you do not know and cannot ascertain the names of the individual fish liver oils which are ingredients of some of your products, we will not for the time being object to the use of language which will state the fact that the active ingredient is a mixture of fish liver oils and that will further reveal the presence and amounts of the vitamins which it contains.\* \* \*

**BAKERY PRODUCTS—INDIVIDUALLY WRAPPED SMALL UNITS**

The ingredient statement of individually wrapped five-cent units of bakery products may cover ingredients common to all varieties, but a supplementary sticker is necessary to declare the characterizing ingredients in any particular package.

TC-197—March 15, 1940

Correspondent's inquiry concerns the problem involved in the labeling of small five-cent bakery units individually wrapped in transparent material. The question is asked whether a label bearing the following wording would comply with the law:

"All our cakes contain the following ingredients: Sugar, Shortening, Eggs, Butter, Milk, Flour, Leavening, Salt, Imitation Flavor. In addition, various varieties may contain one or more of the following ingredients: Cocoa, Spices, Raisins, Nuts, Molasses, Imitation Jelly."



"We think it would be possible to work out some such labeling which would solve the problem you mention and which would at the same time fully meet the requirements of the Food, Drug, and Cosmetic Act, but without discussing the question on the basis of specific cases we are not prepared to say that the identical wording you suggest would completely fulfill the requirements. For example, we believe it would still be necessary to have a supplementary sticker or other form of label on each par-

ticular item, specifically stating which of the 'one or more of the following ingredients' are present in the particular item.

"You also raise the question as to whether it is permissible to print the mandatory label information on a piece of opaque paper and place this paper on the top of the cake under the transparent cellophane wrapping. There is no objection whatever to this form of displaying the mandatory label information provided it is clearly visible through the cellophane."

### CANNED FOODS—PRESENCE OF NITROGEN OR CARBON DIOXIDE

Nitrogen or carbon dioxide in canned foods is not regarded as a chemical preservative which must be disclosed under Section 403 (k).

TC-198—March 15, 1940

Correspondent asks whether it is necessary for the statement "chemically preserved" to appear on the label of canned foods, the air in which has been displaced with nitrogen or carbon dioxide.

"These gases are not regarded as chemical preservatives added to the food. Our opinion is that no conflict with Section 403 (k) of the Act will result by failure to disclose the use of nitrogen or carbon dioxide in the manner mentioned."

### FLOUR—"GUARANTY" STATEMENTS

The use of guaranty statements on flour sacks is discouraged as likely to mislead. If used, the basis and sponsorship for the guaranty should be so clearly set forth as to leave no room for doubt that it has nothing to do with a guaranty under the Act.

There is an inherent objection to such ambiguous terms as "Guaranteed Flour," etc.

TC-199—March 15, 1940

Correspondent's letter discusses guaranty clauses on flour sacks.

"As you point out, a regulation under the new Food, Drug, and Cosmetic Act states, 'No representation or suggestion that an article is guaranteed under the Act shall be made in labeling.'

"In many cases it is a matter of pure speculation as to whether statements like some of those you list would be construed by the purchaser as a guaranty under the Act, and it seems to us the safest policy is to delete all reference to any kind of a guaranty from the label unless the basis and sponsorship for the guaranty is so

clearly set forth as to leave no room for doubt that it has nothing to do with a guaranty under the Act. For example, the last statement you quote, number 24,\* makes it clear, we think, that the product is simply guaranteed to give baking satisfaction and the name of the miller which follows the legend makes it clear who stands behind the guaranty.

"Irrespective of the terms of the Food, Drug, and Cosmetic Act or regulations thereunder, there is an inherent objection to such ambiguous and virtually meaningless terms as 'Guaranteed Flour,' 'Every Bag Guaranteed,' etc."

### GUARANTY UNDER ACT

The guaranty contemplated by Section 303 (c) is more than a warranty between a seller and buyer.

TC-200—March 15, 1940

Correspondent distributes products which he buys under a signed statement on the letterhead of the supplying firm to the

effect that "Our preparations are manufactured in accordance with the new Federal Food, Drug, and Cosmetic Act, Federal Wage and Hour Law, etc., and each item

\* "FAMILY PRIDE is milled from laboratory selected, washed wheat. Every bag of FAMILY PRIDE is warranted to give absolute baking

satisfaction or your dealer will refund the full purchase price. Blank Roller Mills Company, Blankville, Alabama."



made by us carries a money-back guarantee behind it." Correspondent wishes to know whether this statement is sufficient, under Section 303 (c), to furnish him protection from criminal prosecution.

"This statement might be considered in the nature of a warranty between a seller

and buyer, but it is not a guaranty or undertaking as contemplated by the Act. It would accordingly not furnish you any protection from criminal prosecution under the Act."

### SAPONIN—BEVERAGES

When toxic saponins are used in amounts that render beverages or other foods injurious to health, or when the use of saponin has the effect of concealing damage or inferiority, the finished product will be classed as adulterated.

Under Section 403 (i) (2), beverages should be labeled conspicuously with the specific names of each ingredient, including edible saponin, in the descending order of their predominance by weight.

TC-201—March 21, 1940

"When toxic saponins are used in amounts that render beverages or other food products injurious to health, or when the use of saponin has the effect of concealing damage or inferiority, the finished article if shipped within the jurisdiction of the law is classed as adulterated. Manufacturers who use saponin must do so on their own responsibility, but before they use any particular saponin in food they should first assure themselves that it is entirely whole-

some and suitable for food use, and second, that as the product is used it does not serve to conceal inferiority or make the product appear better or of greater value than it is. In this connection we call your attention to Section 402 (b) (3) and (4) of the Act.\* \* \*

"Under Section 403 (i) (2) \* \* \* beverages\* should be labeled conspicuously with the specific names of each ingredient including edible saponin, in the descending order of their predominance by weight."

### MARMALADE

Marmalade is regarded in the category of fruit preserves temporarily exempted from Section 403 (i) (2) if its composition conforms to the advisory standard under the Food and Drugs Act of 1906.

TC-202—March 21, 1940  
(Rescinded, See TC-342)

Correspondent's letter deals with the question of the declaration of ingredients on the label for marmalade.

"We have advised inquirers that, while marmalade is not specifically mentioned in the exemption notice of February 15, 1939, we are disposed to regard it in the same category as preserves with respect to exemption as to the listing of ingredients

on the label. It will not be necessary, therefore, for \* \* \* to list the ingredients on the label for his marmalade, provided it conforms to the advisory definition and standard for marmalade promulgated under the old Act and provided failure to declare the ingredients on labels of marmalade does not result in denying information to consumers to which they are entitled. If this occurs, due notice will be given to marmalade manufacturers."

### CARAMEL

Caramel is an artificial color. Method of label declaration discussed.

TC-203—March 21, 1940

"We cannot share your view that caramel or burnt sugar is not an artificial coloring. Caramel is a pigment made by the artifice of partially breaking down sugar. It is our view that caramel falls squarely within the definition of artificial coloring as set forth in the regulations."

"\* \* \* the Administration is disposed to regard the declaration of added caramel color in beverages in terms of 'Burnt Sugar Coloring' or 'Added Caramel Color' or 'Colored with Caramel' as equally satisfactory."

\* Non-alcoholic carbonated beverages temporarily exempted from 403 (i) (2)—See TC-66.



**FOOD—FUMIGANT—METHYL BROMIDE**

If no trace of a fumigant remains in the finished food, it is not necessary to indicate on label that the article has been fumigated.

The toxicity of methyl bromide makes its use as a fumigant undesirable.

TC-204—March 21, 1940

"If no trace of a fumigant remains in the finished food, it is not necessary to indicate on the label that the article has been fumigated. However, we look with considerable apprehension on your proposal to treat this

food with methyl bromide, which is known to be highly toxic, and you should bear in mind the responsibility which would be yours should any of this fumigant remain in the finished product."

**CANNED FOODS—LABELING OF ROUND CANS**

Letter discusses the use of the so-called intermediate panel for the placement of mandatory information, with particular reference to the labeling requirements for standardized canned peaches and unstandardized canned foods.

TC-205—March 21, 1940

Correspondent requested information concerning a proposal advanced by a trade association with respect to the exclusive use of the intermediate panel on the label of a round can for the label statements required by the Act.

"\* \* \* The plan was to keep this center panel free of any decorative or reading matter other than the required reading matter, and to have this clear space of as large an area as possible. Near the top of the center panel would be printed the net weight statement in type considerably larger than that ordinarily used on canned food labels. Below that, and separated sufficiently to make it stand out by itself, would appear the list of ingredients in the case of fabricated foods, and below this, likewise separated sufficiently to make it stand out, the firm name and address. The reading matter would be printed in large bold type against a uniform contrasting background.

"\* \* \* We have consistently pointed out to inquirers that if they wish to absolutely insure compliance with Section 403 (f) it would seem to us that the obvious thing to do would be to place such information on the main display panel. We have always recognized, however, that it is a question of fact in each case whether or not the position chosen for such information will or will not meet the requirements of Section 403 (f). In our opinion the proposed plan is not in conflict with the suggestions given out by the Administration but is an alternate plan which will, we believe, enable satisfactory compliance with Section 403 (f) in the case of those labels so designed as to leave ample space on the intermediate panel for the exclusive use of the mandatory label information.

"\* \* \* your letter refers to the label design suggested some months ago \* \* \*

for use on canned food labels wherein the mandatory label information required by Section 403 (e) and (i) \* \* \* was prominently set forth on the so-called intermediate panel between the two display panels, this intermediate panel having a width of at least 20 per cent of the total width of the label and being unencumbered with other non-essential reading matter or designs. \* \* \*

"However, the situation is not quite as simple as that when we come to canned foods for which standards of identity under the new law have been promulgated, as in the case of canned peaches, since Sections 401 and 403 (g), and not Section 403 (i), govern the question of position of mandatory label statements in the case of foods for which standards of identity have been promulgated. By referring to page 4921 of the enclosed copy of the December 22, 1939, issue of the Federal Register (Section 27.000 (b) (7)) you will note that the regulation establishing the standard of identity for canned peaches includes a paragraph at the bottom of the third column, (7), which requires that wherever the name 'peaches' appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements required under the previous paragraphs, showing the optional ingredients present, must immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the peaches may intervene. For example, in the case of the halves yellow cling peaches referred to in your third paragraph, carrying a syrup content of 40° Brix, this regulation will require the word 'halves', the words 'yellow cling' (or 'yellow clingstone'), and the words



'in heavy syrup' (if packed in a syrup of not less than 40° Brix) to appear in the manner prescribed in paragraph (7), that is, on each main display panel in immediate proximity to the name 'peaches.' However, it might still be possible for the label to carry that quantity of contents statement and the firm name and address upon the intermediate panel in conformity with the so-called \* \* \* intermediate panel plan.

"We believe this explanation will clear up the point raised in the sixth paragraph of your letter with respect to the position of the syrup statement on canned fruit cocktail labels. In the case of fruit cocktail no definition and standard of identity has as yet been promulgated and there is, therefore, no specific requirement under Section 401 or 403 (g) that the syrup statement appear on the display panel. In the case of this or other as yet unstandardized canned foods the statement must, of course, meet the requirements of Section 403 (f) as to conspicuousness, and if these can be met by including the statement on the intermediate panel, there is no objection to it until such

time as a standard for the product may be promulgated making different requirements."

Correspondent asks whether in a case where the front panel of a round can label lacks adequate space it is permissible to place on the front panel a statement, "Ingredients listed on side panel."

"If the mandatory label information can be placed upon an intermediate panel with such prominence as to meet the requirements as to conspicuousness under Section 403 (f), it is immaterial whether or not the front panel bears the proposed statement, although there is certainly no objection to it. The only point we wish to make is that such a statement, prominently set forth on the front panel, would not justify the listing of the ingredients in such a position on the label as would not meet the requirements as to conspicuousness.

"We have not been able to convince ourselves that in the case of a square package, as distinguished from a round can, compliance with Section 403 (f) is assured when the firm name and other mandatory label information appears elsewhere than on the display panel or panels of the label."

#### IMPORTER DISTRIBUTOR—LABELING—OLIVE OIL

If an importer (in this case of olive oil) is also the distributor, the words "Imported by" followed by the name of the firm need not be further qualified by the word "Distributor."

TC-206—March 21, 1940

Correspondent submitted sample olive oil can and asked whether it would be permissible to lithograph on these tins above the firm name, "Imported by," or whether it would be necessary to state "Distributors."

"The Food, Drug, and Cosmetic Act

states that the name and address of the manufacturer, packer, or distributor should appear prominently on the label. If the firm which imports this article is also the distributor we are not disposed to object to the designation 'Imported by,' followed by the name of the distributor.'

#### CANNED PEACHES, PEARS, AND APRICOTS—LIQUID PACKING MEDIUM

The use of liquid packing medium composed of expressed and strained liquid from canning by-products, mixed with sugar sirup in manner to meet standard for one optional packing medium, would violate identity standards even though no inherent objection thereto. Under Act, application may be made for amendment of standards.

TC-207—March 21, 1940

Correspondent's letter deals with the proposed use of "fructose" and sugar sirup packing medium for canned peaches, apricots, and pears.

"From the description in your letter we conclude that the so-called 'fructose' portion of the proposed ingredient consists of the expressed and strained liquid from irregular pieces of the fruit in the cases of peaches

and apricots, and from irregular pieces, peelings, and cores in the case of pears. The proposal upon which you desire comment is to take this liquid and mix it with sugar sirup, using this mixture as a packing medium. The mixing would be so manipulated in any case that the Brix of the combined packing medium would be in apparent conformity with the sirup density requirement for the usual unmixed sugar sirup



optional packing medium. You cite two advantages—a saving in the cost of the packing medium due to the ‘fructose’ sirup, and an improved flavor for the canned product. You ask whether it will be permissible to pack peaches, apricots, and pears in such a packing medium, and if so, you inquire as to the form of optional ingredients statement.

“While this Administration at the moment sees no inherent objection to the use of this liquid in combination with sugar sirup as a packing medium, nevertheless we are forced to the inescapable conclusion from a consideration of the promulgated standards of identity for these three articles that the standards in their present form preclude the use of such a mixture and that, therefore, canned apricots, peaches, or pears packed with the packing medium you refer to would be illegal. This conclusion is

based upon the language used in the pertinent parts of the standards of identity for these three products, which specifically refer to the addition of ‘one of the following optional liquid packing media.’ This list of optional liquid packing media does not include the liquid which is expressed and strained from the by-products of canning these fruits such as you mention.

“While certainly it is not the disposition of this Administration to put any obstacle in the way of progress in the direction of economy or improvement of flavor, you can see that we are wholly without authority to make any administrative ruling at variance with the statute and the standards thereunder. The law does, of course, provide a means of amending promulgated standards, and that is the course laid down in Section 701 (e), providing for the holding of a public hearing to amend a regulation.”

#### RUBBING ALCOHOL—ISOPROPYL—LABELING

Since the designation “Rubbing Alcohol Compound” is associated in minds of consumers with product made from ethyl alcohol, isopropyl alcohol products should be clearly designated as “Isopropyl Alcohol Rubbing Compounds.” Letter discusses labeling.

TC-208—March 21, 1940

“\* \* \* We have in all cases informed the manufacturer that since the designation ‘Rubbing Alcohol Compound’ has been used and is associated in the minds of consumers with a product made from ethyl alcohol, we believe that isopropyl alcohol products should be clearly designated as ‘Isopropyl Alcohol Rubbing Compounds’ and not ‘Isopropyl Rubbing Alcohol Compounds,’ since the latter expression might create the impression that the word ‘isopropyl’ is merely a brand name and not the type of alcohol used.

“\* \* \* It is our opinion that no wording should intervene between ‘isopropyl’ and ‘alcohol.’

“\* \* \* the term ‘proof’ is not applicable to isopropyl alcohol and should be deleted \* \* \*.

“\* \* \* Since the term ‘alcohol rubbing

compound’ has become associated with preparations containing 70 per cent ethyl alcohol, we would not be disposed to criticize the use of some such term as ‘isopropyl alcohol rubbing compound’ on an article containing a similar quantity of isopropyl alcohol.

“An article which contains only 50 per cent of isopropyl alcohol is not isopropyl alcohol, but a diluted isopropyl alcohol. There is no objection to the distribution of such a preparation under appropriate labeling \* \* \*.

“An article which contains 35 per cent of isopropyl alcohol in water would not be entitled to the name Isopropyl Alcohol Compound for the reason pointed out by Regulation (b) under Section 502 (a). Such a product would not contain a sufficient proportion of isopropyl alcohol to produce the effects expected from an alcohol rub.”



## POTATO CHIPS AND STICKS—DESIGNATION OF OIL OR SHORTENING USED

The oil or shortening in which potato chips and sticks are prepared need not be declared by its specific name. The term "Vegetable Oil" or "Vegetable Shortening" may be used, if a vegetable oil is used.

TC-209—March 21, 1940

Correspondent requests information on labeling of potato chips from the standpoint of Section 403 (i) (2).

"\* \* \* the Administration has had occasion to give consideration to the practical difficulties attendant upon a declaration of shortening ingredients by their specific names on baked goods, and as a result, we have advised the baking industry that, in view of the impracticability of always anticipating the particular shortening which may be used at any given time, we will regard the term 'Shortening' in the list of ingredients as in substantial compliance with Section 403 (i) (2).

"We are inclined to take the same view with respect to the declaration of the oil in which such articles as potato chips are fried, and we will therefore not insist upon a declaration of the specific frying oil in declaring the ingredients on the label of potato chips, provided the presence of the

frying oil is made known by some such term as 'Fried in Vegetable Oil' or 'Cooked in Vegetable Oil,' if a vegetable oil is used.

Comment was given on the label for an article consisting of potato sticks French-fried in vegetable shortening with salt added.

"\* \* \* We may say, however, that a label for such a combination should state that the product consists of potato sticks fried in vegetable shortening with salt added. We have not insisted that the name of the specific shortening be declared under such circumstances, but, if it later develops that the use of the term 'vegetable shortening' instead of naming the specific shortening, results in depriving consumers of information to which they are entitled under the Act it would then be necessary to rescind permission to use the designation 'vegetable shortening' and require the name of the specific shortening."

## CAVIAR

The name of fish from which eggs are taken should be part of name and should appear in substantially the same style and size of type as the word "Caviar".

The temporary exemption of canned fish roe from Section 403 (i) (2) does not extend to ingredients not ordinarily used.

TC-210—March 21, 1940

Correspondent submits for comment specimen labels for caviar.

"For your information we enclose a copy of Item 21 on the use of the term 'Caviar.' While there is no objection to the designation of your product as 'Whitefish Caviar' in accord with this announcement and in the light of your statement that it is prepared from roe taken from fish of the whitefish family, the labels are nevertheless in our opinion definitely misleading because of the relatively great prominence given to the word 'Caviar' as compared with that given to the word 'Whitefish.' In our opinion the label should be redesigned so that the words 'Whitefish Caviar' appear in substantially the same size and style of type.

"Certain foods have been exempted from label declaration of ingredients pending the formulation of standards under the new law. Among these appears canned fish roe. While canned caviar may be regarded as coming within this exemption, this would not obviate the necessity of declaring on the label any ingredient not normally or usually used in the preparation of caviar. It is our understanding that sugar is not ordinarily used and therefore should be declared on the label. \* \* \*

(Item 21, to which reference is made, states in effect that the term "caviar" can properly be applied to any kind of fish eggs prepared after a special method. The eggs first prepared and most extensively used were those of the sturgeon, and to many people the term "caviar" is synonymous



with "sturgeon caviar." In view of this fact and of other considerations, it is believed that the name of the particular fish from whose eggs caviar is made should appear on the label. In the case in point an appropriate label would be "whitefish caviar." No objection will be raised to the use of the term "caviar" on a product pre-

pared according to the usual method and made from the roe of whitefish, provided the name of the fish is given in conjunction with the word caviar. The Item also states that harmless coloring may be used in a product of this kind provided a clear declaration of the presence of the added color is made on the label.)

### VIGNETTES ON LABELS—SALMON LABEL—LETTUCE LEAF

The use on labels of vignettes which depict articles not present in the can (for example, a vignette of a salad on a lettuce leaf on the label of a can of salmon), may or may not mislead, depending on the circumstances.

TC-211—March 21, 1940

Correspondent asks whether it will be permissible under the new Food, Drug, and Cosmetic Act to show lettuce leaves on a dish in connection with a vignette display of canned salmon, canned tuna, or canned shrimp where the salmon, tuna, or shrimp is displayed in the form of a salad placed on top of the lettuce leaves.

"The new law \* \* \* prohibits any label statements or designs which may be false or misleading in any particular. Therefore \* \* \* it is a question of fact in each case whether or not, in the light of all the circumstances, the label would be misbranded by reason of the display of a vignette of

the kind you have in mind. If such a vignette merely suggests a form in which the contents of the can may be served and does not suggest the presence in the can of ingredients which are not present and does not in any other manner give a misleading impression regarding the contents of the can, there should be no objection to it. Probably no one would expect a lettuce leaf in canned salmon, tuna or shrimp. However, it is possible that a vignette of the kind you describe might suggest that the contents of the can were suitable for the preparation of a salad, whereas they might not be of the particular grade or quality usually employed for that purpose. \* \* \*

### SALAD DRESSINGS—MAYONNAISE OR CHILI SAUCE—CEREAL STARCHES

In the case of a dressing containing mayonnaise or chili sauce as an ingredient, the ingredients of the mayonnaise or chili sauce need not be declared.

Cereal starches in salad dressings should be individually named.

TC-212—March 21, 1940

"In the case of a dressing containing mayonnaise, or one containing chili sauce, as an ingredient, we are not disposed to insist that the ingredients of the mayonnaise or chili sauce be declared. If it develops, however, that by omission of the statement of the constituent ingredients of the mayon-

naise and chili sauce consumers are being deprived of information to which they are entitled under the Act, it will, of course, be necessary to rescind the above opinion.

"Cereal starches present in dressings should not be grouped under this general term, but the particular starches should be named."

### FISH FILLETS—SODIUM NITRITE

Letter discusses proposal to preserve fish fillets in brine containing sodium nitrite. The Administration is not satisfied that the treatment of fish with chemicals as a means of keeping the fish is to be encouraged, because of the likelihood that in some hands it will bring about relaxation of efforts in handling fresh fish properly.

TC-213—March 21, 1940

The Administration was asked to comment on the proposed use of a brine for the treatment of fish fillets to be sold in inter-

state commerce, the brine containing an amount of sodium nitrite among other ingredients.



"\* \* \* The material which you submitted states that the nitrite found in brined fillets, and in fish steaks which have been made from brined fillets, averages about 40 parts per million calculated as sodium nitrite.

"The responsibility for the use of this treatment, so far as the Federal Act is concerned, would be that of the individual or firm who shipped the fish so treated in interstate commerce. In the first place, of course, he should satisfy himself as to whether or not the sodium nitrite would constitute an added deleterious ingredient. If suitable for use in foods from this standpoint it would then be his responsibility to see that fish fillets so treated bear a con-

spicuous statement showing the presence of this chemical preservative. Furthermore, the treatment should not be applied if in any case it results in the concealment of damage or inferiority or makes the product appear to be better or of greater value than it is.

"This Administration is not at all satisfied in its own mind that the treatment of fish with chemicals as a means of improving and keeping the fish is to be encouraged because of the likelihood that in some hands it will bring about relaxation of efforts in the direction of prompt handling and proper storage of fresh fish."

---

### FISH SHIPPED BY FISHERMEN TO WHOLESALERS

Fish shipped by fishermen to wholesale markets in large boxes or barrels are not considered to be in package form, but it is suggested that the containers bear the name of the fish.

TC-214—March 21, 1940

"You point out that fresh fish are shipped by fishermen or the shipper in boxes or barrels to wholesale markets for distribution in the same manner in which agricultural products are marketed. You advise that fishermen have no facilities for weighing or sorting their catch and merely pack their fish in any suitable container with a sufficient quantity of ice to keep it until it arrives at market, tacking a tag on the package and handing it over to the expressman. You state that when the fish arrives at the market, it is sold by weight to retailers. You ask specifically whether such fishermen will be within the law by continuing to ship their fish in this manner.

"The facts set forth lead us to the conclusion that such containers do not constitute food in package form but are merely convenient receptacles for conveying the fish from one place to another as a preliminary to later sale of the fish by weight in retail markets. We are not inclined, therefore, to insist upon the net weight statement or the statement giving the firm name and address appearing upon such containers, although we have some reservation as to whether the Act would also permit the omission of the common or usual name of the fish. We suggest that, in order to assure compliance, the boxes bear the name of the fish."

---

### "BEVERAGE BASE"

There is no objection to the designation as a beverage base of a preparation to be mixed with sugar and water to make a beverage, provided the name is accompanied by a conspicuous statement that the article is to be used with sugar.

TC-215—March 21, 1940

"There would appear to be no objection to designation as a beverage base of a preparation to be mixed with sugar and water to make a beverage, provided the name is accompanied by a conspicuous statement to the effect that the article is to be used with sugar. As you know, there are on the market complete beverage bases, that is,

articles to which it is necessary to add only water to make a finished beverage. The purchaser should be able to readily distinguish, by means of the name or accompanying statement, between such articles and those to which sugar must be added by the purchaser before beverages can be made from them."



### MINCEMEAT—PIE LABEL—INGREDIENT STATEMENT

The ingredient statement of mincemeat should include water if not all removed during manufacture.

The label of a mince pie may declare "mincemeat" as the common name if the mincemeat is of normal composition.

TC-216—March 21, 1940

"It is our understanding that mincemeat does not come within the scope of the Meat Inspection Act enforced by the Bureau of Animal Industry. It is, therefore, amenable to the provisions of the Food, Drug, and Cosmetic Act if shipped in interstate commerce.

"\* \* \* it will be necessary to declare water among the ingredients of mincemeat if water which is added is not all removed in the process of manufacture.

"Flavors and other ingredients which are normal to mincemeat can, of course, be

used provided they are properly declared on the label."

"The term 'mincemeat' in our opinion is sufficiently well understood by the consumer to justify this name being used as the common or usual name for the ingredient in the case of mince pies, provided the mincemeat is of normal composition. Where, however, fillers or thickeners are employed so that the product is not the article commonly understood as such, a label declaration showing these ingredients should appear."

### POTATOES IN SACKS

Potatoes in sacks are food in package form and must bear the required label designations.

TC-217—March 21, 1940

"Potatoes in sacks constitute food in package form and should bear the label information required under Section 403 (e), that is, the net weight and the name and place of business of the manufacturer," (or grower), "packer, or distributor. Under Section 403 (i) (1) the name of the article, 'Potatoes,' should be declared. In order to comply with Section 403 (f) the required information should be prominently set forth on the face of the sack itself or on a conspicuous securely affixed tag. It is not necessary to state the grade of the potatoes but if any grade is stated it must, of course, not be false or misleading in any particular."

Correspondent states that bags are furnished to the farmers with a brand name, the word "Potatoes", and the net weight statement printed thereon, but without any firm name; the potatoes are hauled to town, loaded in cars, and bought by various buyers on a cash track basis.

"There would be no objection to securely affixing to such bags at the time of such cash purchase before interstate shipment, tags bearing the name and place of business of the distributor; or, tags bearing the name and place of business of the farmer who packs the bags of potatoes could be affixed at the time of packing."

### USE OF PUMPKIN IN BAKED GOODS

The addition of canned pumpkin to mixes for baked goods in order to give the dough the appearance of having a quantity of egg in it would constitute adulteration under any form of labeling.

TC-218—March 21, 1940

Correspondent asks whether it is permissible, so far as bakery laws are concerned, to add canned pumpkin to mixes for sweet rolls and doughs of this type. Correspondent's customers state that their reason for wishing to add the pumpkin is to give the dough the appearance of having a quantity of egg in it.

"\* \* \* Such a practice, in our opinion, can only operate to the deception of the consuming public and is to be unqualifiedly discouraged. \* \* \* The new Food, Drug, and Cosmetic Act \* \* \* classifies a food as adulterated if any substance has been added to it or mixed with it so as to make it appear better or of greater value than it is. In our opinion, bakery products or any



other food containing pumpkin, which gives the appearance of having an egg content when no eggs are present, or a greater egg content than is the case, would be an adulterated article under any form of label-

ing. The fact that pumpkin is a wholesome food product in itself does not constitute justification for its use in a manner which constitutes adulteration."

### FLAVORING COMPOUNDS—COAL-TAR COLORS

Flavoring compounds containing coal-tar colors do not require certification notwithstanding that they contain sufficient color to color the finished product.

TC-219 (amplifies TC-171)—  
March 21, 1940

Correspondent requests comment concerning the application of the coal-tar color regulations to mixtures of flavors with certified colors in sufficient amount to color the food to which such mixtures are added.

"We did not mean to convey the impression \* \* \* that all mixtures, such as soft drink powders and gelatin desserts, would need to be certified in their final form to meet the requirements of the Federal Food, Drug, and Cosmetic Act. When the products involved are, in fact, fabricated foods which may be used by the housewife or in

manufacturing by the simple addition of substances such as water to prepare the final product, we do not believe that simply because they contain sufficient color to color the finished product they need to be certified. On the other hand, if the articles are sold primarily because of their ability to impart color and the flavoring or other ingredient is added purely incidentally and, perhaps, in an attempt to remove it from classification as a color, we then believe that the mixtures would need to be certified."

*Note:* TC-171 in all files should be marked with a notation calling attention to the existence of TC-219.

### HAIR-TONICS—TONICS

An article offered for its tonic action is a drug under Section 201 (g).

Administration is not familiar with any substances which will produce a tonic effect on the hair, and has suggested that some other term than "hair tonic" would be preferable for hair preparations.

TC-220—March 21, 1940

Correspondent inquires regarding the status of hair tonic or tonics for various purposes under the provisions of the Food, Drug, and Cosmetic Act.

"It is our opinion that an article offered for its tonic action is a drug, as this term is defined in Section 201 (g) of the Act. While we have expressed no final opinion

in regard to the propriety of the term 'tonic' when applied to hair preparations, we may state that we are not familiar with any substance or mixture of substances which will produce a tonic effect on the hair. For this reason we have suggested to several correspondents that some other term than 'hair tonic' would be preferable for preparations of this type."

### FRUIT FLAVORS—LABELING—GELATIN

The letter discusses the labeling of flavors containing a substantial amount of one fruit (strawberry) and small amount of another natural flavor (raspberry), fortified with essential oils and plant extractives.

Letter also discusses method of designating the flavor of gelatin and other foods in which such reinforced flavor is used.

TC-221—April 11, 1940

Visitor at interview submitted a manufacturing formula for a flavor made from strawberries and a small amount of raspberries, fortified with certain essential oils

and plant extractives. Comment on the labeling to be used on such a product was offered in a letter, as follows:

"According to the formula submitted by you, your product is manufactured from a



substantial proportion of strawberries, namely, forty-five pounds of fruit per gallon. In addition, it contains a small percentage of raspberry extract and varying quantities of five plant extractives or essential oils.

"While the amounts of plant extractives and essential oils are small, they contribute materially to the flavor and odor of the article as shown by an organoleptic examination of the specimen which you left here. We are of the opinion, therefore, that it would be misleading for you to name this article 'Strawberry Extract' as you propose. This name would not meet the requirements of the \* \* \* Act. In view of the substantial proportion of fruit used in the manufacture of the product, we are not disposed to class it as an imitation strawberry flavor. So far as the particular product which you submitted here is concerned, we believe that it will not be a misbranding under the Act to name it 'Strawberry Flavor, Reinforced with natural flavors,' all words in the name being displayed with equal prominence. The name should, of course, be followed by an appropriate list of ingredients in the order of their importance, as for example, 'Strawberry Flavor, with a small proportion of Raspberry Flavor, and Extract of St. John's Bread, Fennel, Garlic, and Oils of Orris and Sage.' There should also be

listed on the label the names of the solvents.

"The name such as 'Strawberry Flavor, Reinforced with natural flavors' should not be applied to a flavor unless more than one-half of the flavoring strength of such flavor is derived from strawberries. Since you did not submit here a specimen of the mixture of natural flavors for direct comparison of its flavoring strength with that of the specimen of strawberry extract which you left here, we cannot state definitely that more than one-half of the flavoring strength of your fortified flavor is derived from strawberries. It will be your obligation to establish this if you decide to use the name quoted above.

"A similar name may be applied to gelatin dessert powders and flavoring sirups flavored with this reinforced flavor. The label of the gelatin dessert powder would thus read 'BLANK BRAND GELATIN DESSERT POWDER, STRAWBERRY FLAVOR REINFORCED WITH NATURAL FLAVORS, a mixture of sugar, gelatin, citric acid, flavor, and U. S. Certified Color,' and that of the flavoring sirup 'BLANK BRAND SIRUP, STRAWBERRY FLAVOR REINFORCED WITH NATURAL FLAVORS. Contains sugar, sirup, citric acid, flavor and U. S. Certified Color.' \* \* \*"

### CANNED PEACHES AND SIMILAR FRUITS—CUT-OUT AND PUT-IN SIRUPS

Letter discusses the distinction between cut-out sirups described in U. S. Standards for Grades (Agricultural Marketing Service), and put-in sirups for which specifications are given in definitions and standards of identity promulgated under the Federal Food, Drug, and Cosmetic Act.

TC-222—April 11, 1940

Correspondent requests information regarding the strength of sirups to be used on canned peaches. In reply he was referred to the "Federal Register" for December 22, 1939, on page 4921 of which is given the definition and standard of identity for canned peaches. Subsection (a) (2) of this regulation gives the definitions of the put-in sirups to be used as liquid packing media on canned peaches, and Subsection (b) (2) gives the labeling requirement for each of these put-in sirups.

"The definitions of different types of sirups which you quote from the U. S. Standards for Grades refer to cut-out strengths of sirups. These are issued by the

Agricultural Marketing Service of this Department for use in their certification of commercial grades of canned clingstone peaches, and are not promulgated under the Food, Drug, and Cosmetic Act. It is, however, our experience that sirups of the strengths given in the definitions and standards of identity for canned peaches, used with products which meet the standard of fill of container for canned peaches given on page 4922 of the Federal Register, will in the majority of cases give cut-out sirups within the ranges specified in the U. S. Standards for Grades."

(Applicable also to Canned Apricots, Canned Pears, and Canned Royal Anne Cherries.)



**PECTIN PREPARATIONS—LABELING**

The letter discusses the labeling of pectin preparations.

TC-223—April 11, 1940

"Section 403 (i) (1) of the Act requires that mixtures that are not standardized shall be labeled with the common or usual name of the food if any there be. The statements made in your letter \* \* \* and our own observations lead us to believe that the common or usual names for certain commercial mixtures of pectin and dextrose are 'Pectin 100 grade,' 'Pectin 150 grade,' etc. In order to comply with the provisions of Section 403 (i) (2) it will be necessary for such names to be directly followed by a conspicuous list of the specific names of all ingredients, as for example, 'Dextrose, pectin,' and the specific name of each salt added for buffering purposes. We believe that it will be necessary to include a statement on the label of such a mixture to the effect that one pound of it will serve to set 100 pounds (150 pounds, etc.) of sugar.\*

"A mixture of pectin, sugar, and water, bearing a purely fanciful name should be

labeled with the specific name of each ingredient in the order of predominance and with a statement indicating the jellying strength of the mixture. The list of the ingredients should be displayed with the degree of conspicuousness required by Section 403 (f) of the Act.

"We cannot of our own knowledge state whether or not the name 'Effervescent pectin' is a common or usual name for a mixture of the indicated composition. We are inclined to believe that the name of such a mixture should show clearly that it is not 100 per cent pectin. A name such as 'Effervescent pectin mix' directly followed by the specific names of the ingredients in the order of their predominance, would probably meet the requirements of the law. In this case also the label should bear a statement indicating the jellying strength of the mixture."

**ALCOHOLIC BEVERAGES—BEER—FEDERAL ALCOHOL ADMINISTRATION**

While alcoholic beverages and beer are subject to the Federal Food, Drug, and Cosmetic Act, the Administration will continue to leave to the Federal Alcohol Administration the regulation of the labeling of these products under the more specific Federal Alcohol Administration Act.

TC-224—April 11, 1940

"While we have indicated that cordials, liqueurs, wine, and whiskey are subject to the Act, we will continue, as in the past, to leave to the Federal Alcohol Administration the regulation of the labeling of these alcoholic beverages under the more specific Federal Alcohol Administration Act.

"While beer is classed as food under the Act and would, therefore, be subject to the

adulteration and misbranding provisions of that Act when shipped within its jurisdiction, we expect to continue our policy of not duplicating the work of the Federal Alcohol Administration with respect to the labeling of such products. That Administration, as you know, is charged with the enforcement of specific legislation dealing with alcoholic beverages."

**"MALT SYRUP"—"MALTED CEREAL SYRUP"**

Administration has held that "malt syrup," without qualification, means barley malt syrup. If that name is used to designate any other product it would be misleading. A product of that type made from barley and other cereals would be more appropriately named "malted cereal syrup."

TC-225—April 11, 1940

Correspondent requests information concerning the labeling requirements for malt syrup.

"A statement of ingredients is required to appear on the label of a food, provided it is fabricated from two or more ingredients, and provided further that a definition and

\*To clarify the label statement "100 grade", "150 grade", etc., the meaning of which might

not otherwise be understood.



standard of identity has not been prescribed by regulations. \* \* \* No such regulations have been issued pertaining to malt syrup. This Administration has been holding that 'malt syrup,' without qualification, means barley malt syrup. If this name is used to designate any other product, in our opinion it would be misleading under section 403 (a) of the Act. A product of this type made from barley and other cereal

or cereals would be more appropriately named 'malted cereal syrup.'

"If such a product be used as an ingredient of another food, its presence of course should be declared on the label along with the other ingredients. We believe that some expression such as, for example, 'malted cereal (barley and corn) syrup' would be appropriate for a product of this type."

### FRESH FRUITS AND VEGETABLES (LETTUCE)—"BOX-END" LABELS

The quantity of the product contained in boxes and crates of fresh fruits and vegetables should be set forth. In the case of lettuce, a statement of the amount of food in terms of dry measure and the number of heads will suffice.

TC-226—April 11, 1940

Correspondent asks regarding the labeling requirements of the Act as they may apply to box-end labels that ordinarily go on the end of boxes and crates of fresh fruits and vegetables; he submits a paper label reading "\* \* \* Brand Iceberg Lettuce", these words being followed by the name of the packer.

"In our opinion, in order to insure full compliance with the labeling requirements of the law, the quantity of the product in

the package should also be plainly set forth on the label in connection with the article. The form of indicating the quantity might differ in the case of different types of products in accordance with consumer understanding and good commercial practice. In the case of lettuce, we would be disposed to regard the quantity of contents requirements as being met by a statement of the amount of food in terms of dry measure and the number of heads in the box or crate."

### SODIUM PERBORATE

The present evidence of possible harm to users of product containing large percentage of sodium perborate requires a specific warning with respect to the effects the article may produce. Additional scientific evidence may demonstrate that indiscriminate distribution is a violation of Section 502 (j).

TC-227—April 11, 1940

Correspondent had previously been advised that in our opinion it is inappropriate to designate as "Sodium Perborate Compound Flavored" a product consisting of 96 per cent sodium perborate and 4 per cent magnesium oxide, with flavoring.

\* \* \* We note your statement that a change in the designation of this product would result in loss of sales. The Administration of course does not want to suggest the adoption of business practices which may be financially hurtful to the purveyor, but we cannot escape the conclusion that under the provisions of the Food, Drug, and Cosmetic Act the present designation of this article is not appropriate.

\* \* \* While we are not prepared at this time to express the definite opinion that the

article is dangerous to health, and, therefore, misbranded under any form of labeling which would permit its indiscriminate sale to the public, there is, as you no doubt know, considerable evidence that the article is capable of producing definite pathological changes in the oral mucosa and anterior pharynx and on the tongue of a far from negligible proportion of users. It is by no means certain that rinsing the mouth with warm water after use will effectively prevent such pathological changes in the tissues. In our opinion, a much more specific and definite warning with respect to the effects this article may produce is a minimum requirement of the Act.

"If additional data resulting from scientific evidence should demonstrate that the potentially harmful characteristics of the



article are such as to render its indiscriminate distribution inimical to the public health, such distribution will be regarded as constituting a violation of Section 502 (j)

of the Act unless the labeling is such as to preclude sale and use of the article except by or upon the prescription of licensed practitioners."

### USE OF COLOR IN TABLETS (SODIUM BICARBONATE) DESCRIBED IN NATIONAL FORMULARY

Sodium bicarbonate tablets colored pink may be designated by the official National Formulary name.

TC-228—April 11, 1940

Correspondent asks whether sodium bicarbonate tablets colored pink can properly be designated by the official National Formulary name.

"The National Formulary does not state whether or not the tablets recognized in it are colored. It makes no reference to the excipients, flavoring material, or coating of such tablets. It does not even specify

the amount of the active ingredient contained in the tablets. The monographs are written in the most general terms, apparently for the purpose of including tablets sold under the official titles regardless of their shape, size, color, potency, or composition other than the identity of the active ingredient. Of course, only certified dyes should be used if the coloring matter is a coal-tar dye.\* \* \*"

### TOOTH POWDER—"HEALTHFUL" ON LABEL

The word "healthful" on the label of a tooth powder will bring it within the classification of "drug".

TC-229—April 11, 1940

Correspondent asks whether the word "healthful" on the label of a tooth powder will bring the product within the classification of the term "drug".

"Final decision in such matters rests solely with the courts. However, it is our opinion, based on court decisions under the Food and Drugs Act of 1906, that a claim of this type will class the article as a drug."

### PRUNES—CANNED "BREAKFAST PRUNES IN SYRUP"

The designation "Breakfast Prunes in Syrup" is inappropriate if dried prunes are used.

TC-230—April 11, 1940

Correspondent's letter deals with the labeling of canned "Breakfast Prunes in Syrup" prepared from dried stock.

"While the term 'Prunes' formerly was generally understood to refer to the prune plum after drying, since that was practically the only form in which it appeared on the market as a food throughout the country

in general, there has developed a widespread practice in recent years of canning the fresh prune plum both in water and in syrup, so that there is a certain degree of ambiguity in the unqualified word 'prune' for the product you have in mind, which, in our opinion, should be avoided by referring to the article as 'dried prunes.'"

### NARCOTICS—HYPODERMIC TABLETS IN SMALL CONTAINERS

Letter discusses the labeling of narcotics in small containers. If hypodermic tablets are in such small vials that it is not possible to place on the label the "caution statement," the caution should be placed on the carton containing the vials.

TC-231—April 11, 1940

Correspondent states that the label submitted with his letter is the maximum size label which will fit on the bottle required

for morphine sulfate tablets  $\frac{1}{2}$  grain. He inquires whether the phrase "for prescription use only" may be used in lieu of the phrase "to be used only by or on the prescription of a



physician" referred to in paragraph (b) (2) of the regulations under Section 502 (f).

"Since a product of this character is subject to regulation under the Harrison Narcotic Law, the Administration will offer no objection to the use of the phrase 'for prescription use only,' provided it is placed conspicuously upon the label in type comparable to other statements appearing thereon.

Correspondent submits a proposed label for  $\frac{1}{4}$  grain "Hypodermic Tablets Mor-

phine Sulfate" and inquires whether the caution statement in Regulation (b) (2) under Section 502 (f) must be placed upon the label, since hypodermic tablets are dispensed or prescribed only by a physician.

"If the vials are of such small diameter that it is not possible to place on the label the caution statement, \* \* \* it is suggested that such caution be placed on the carton containing these vials."

#### PRETZELS—CAUSTIC LYE DIP—SODIUM CARBONATE

Cans of pretzels containing six or ten pounds should comply with Section 403.

Caustic lye dip in which pretzels are immersed is changed to sodium carbonate in baking process. It is suggested, therefore, that a statement be made on label indicating that a trace of sodium carbonate may be present.

TC-232—April 11, 1940

"In our opinion, cans of pretzels containing six or ten pounds should bear all of the mandatory label information required under Section 403 of the Act \* \* \*.

"Your second inquiry relates to the question of requiring label declaration of caustic lye, in a two per cent solution of which pretzels are immersed before baking. It is generally agreed that in the baking process, this caustic lye is changed to sodium carbonate. Under the circumstances, we are

inclined to feel that the declaration of the caustic lye would be inappropriate. Whether or not the courts will interpret the law as requiring the residual trace of carbonate that may be present in the finished product to be declared is, perhaps, a matter of speculation at this time. We suggest, however, that in order to insure compliance with the requirements of Section 403 (i) (2), some statement be made to indicate that a trace of sodium carbonate may be present."

#### MONOSODIUM GLUTAMATE—ARTIFICIAL FLAVOR

Monosodium glutamate, when added to a food, is considered to be an artificial flavor whose presence must be declared.

TC-233 (See TC-340)—April 11, 1940

"Monosodium glutamate when added to a food is considered to be an artificial flavor, as defined in the regulations under Section 403 (k) of the Food, Drug, and Cosmetic Act \* \* \*. When added to a food the presence of an artificial flavor must be declared on the label. Monosodium glutamate may be declared as 'artificial flavor,' 'artificially flavored,' 'Monosodium glutamate,

an artificial flavor'; or 'Vegetable protein derivative, an artificial flavor.' If in any case the addition of monosodium glutamate has the effect of concealing damage or inferiority, or of making the article appear to be of better or greater value than it is, the article would be classed as adulterated even though the label declared the presence of the artificial flavor."

#### MUSTARD—LABELING

A mixture of mustard and mustard bran to which an artificial mustard oil or cayenne pepper is added becomes imitation prepared mustard and should be so labeled.

TC-234—April 11, 1940

"\* \* \* If the mustard component predominates, the article may be designated as

'Prepared Mustard and Mustard Bran'; otherwise, the article falls into the imitation class. In your case, the addition of



artificial mustard oil emphasizes even more the imitation characteristics of the article, and we therefore are of the opinion that your product is an imitation prepared mustard and should be so labeled.

"In reviewing your formula we note that you contemplate adding one-half ounce cayenne or red pepper to each tank. On products containing more mustard than mustard bran the label designation 'mustard and mustard bran' has been regarded as suitable. Where the amount of mustard

bran exceeds the mustard it is required that the product be labeled as an imitation. The amounts of mustard and mustard bran in your product are nearly equal. Under such circumstances, the addition of red pepper would appear to us to give the product more of the pungency ordinarily associated with greater quantities of mustard. Under the circumstances it is our opinion that the only suitable manner of selling this product with the added cayenne pepper would be as an imitation prepared mustard."

### PICKLES

"Service and Regulatory Announcement, Item 225," used under Food and Drugs Act of 1906, may be used as a guide in declaring the quantity of contents of jars of pickles.

Pickles in gallon cans for sale to manufacturers of other products are food in package form.

TC-235—April 11, 1940

"Under the terms of the new law no specific announcement has been issued as to the definite weights of pickles that should be contained in jars of different sizes. The enclosed Service and Regulatory Announcement, Item 225, was used as a guide in the enforcement of the Food and Drugs Act of 1906. Under the new law the regulation with respect to the declaration of net contents is somewhat different than under the law of 1906 and Regulation (e) (2) under Section 403 (e) \* \* \* requires that the statement of the quantity of contents be declared in the terms generally used by the consumer to express the quantity of such food and which give accurate information as to the quantity thereof. Since the passage of the new law we have not had opportunity to investigate the terms generally used by the consumer and pending a determination of consumer understanding and practices we believe it would be safe to follow the principles established in the Service and Regulatory Item as a guide in declaring the contents of pickles. The passage of the new law has increased the duties of the Administration

greatly but it is our expectation at the earliest opportunity to investigate the declaration of the quantity of contents of pickles, with a view to establishing definite requirements."

Item 225 says in part:

"Pickles in brine, vinegar, or sweetened vinegar, may be marked in terms of weight of the drained product, of liquid measure of the drained article, or of numerical count in accordance with the usual trade practice for the particular article. This opinion is not intended to apply to chowchow or similar relishes, the quantity of which may be declared as a whole."

Correspondent asks whether the ingredient clause needs to be stamped on a gallon can of pickles inasmuch as the cans are sold only to bulk trade.

"Pickles packed in gallon cans are unquestionably food in package form and Section 403 (e) and (i) (2) will, in our opinion, necessitate placing the required label statements on these cans even though they are used by manufacturers for the further manufacture of other food products."

### CANNED PEACHES—"SOLID PACK PEACHES"

Solid pack yellow cling peaches which contain no liquid packing medium are not embraced by the standard for canned peaches. They may be sold under their common name, "Solid Pack Peaches".

TC-236—April 11, 1940

Correspondent inquires whether the sub-standard legend must appear on the label

of solid pack yellow clingstone peaches which contain no liquid packing medium.

"\* \* \* as the product does not contain



any liquid medium, it is not \* \* \* embraced within the promulgated standard for canned peaches. It may for this reason be sold under its common or usual name as "Solid

Pack Peaches" in accordance with Section 403 (i) (1) of the Food, Drug, and Cosmetic Act."

### PROCESS CHEESE—ARTIFICIAL COLOR

Pending the promulgation of a standard of identity, process cheese made from normally colored cheddar cheese need not be labeled to show artificial color.

TC-237—April 11, 1940

"This refers to the question \* \* \* whether declaration of artificial color in process cheese is exempted under Section 403 (k) in the proviso which names 'butter, cheese, or ice cream.'

"Answering directly your question, we do not regard process cheese as cheese unqualified within the meaning of the Act and this by reason of the adoption a number of years ago of a definition and standard for process cheese which establishes the identity for it apart from that applicable to Cheddar cheese. A strict interpretation of 403 (k), therefore would in our opinion not include in the exemptions process cheese, to which artificial color had been added in any manner. We do recognize, however, the fact that this definition and standard refers

to ordinary Cheddar cheese as one of the components—in fact the chief component—of process cheese, and that Cheddar cheese in the United States, by Act of Congress, is permitted to contain artificial color. \* \* \* so far no standard of identity has been promulgated for process cheese under the present Act, nor is one in immediate contemplation. Until a standard of identity is established, it is only logical to expect the industry to observe the former definition as guiding. Until such time as a new definition and standard of identity for process cheese is established under the existing law, this Administration will not be disposed to insist upon a label declaration of artificial color in the case of process cheese made from normally colored Cheddar cheese."

### CONFECTIONERY—RESINOUS GLAZE—SHELLAC, CARNAUBA WAX, AND STEARIC ACID

Letter discusses the labeling of confectionery containing harmless resinous glaze, and classification of shellac, carnauba wax, and edible stearic acid in confectionery.

TC-238—April 11, 1940

"Under Section 402 (d) confectionery may contain harmless resinous glaze not in excess of four-tenths of one per centum. Shellac used in confectionery is classed as a harmless resinous glaze, provided it is free from poisonous or deleterious impurities.

"Under the provisions of Section 403 (i) (2), confectionery that is glazed with shellac should bear on the label a declaration to that effect. An appropriate declaration, in our opinion, would be 'Shellac glaze' or 'Glazed with shellac.'

"On some of your revised labels the expressions 'candy glaze' and \* \* \* are used in the statement of composition. We feel that \* \* \* 'candy glaze' does not indicate specifically the ingredient used.

"We are not disposed to insist upon a declaration of the presence of the small amount of harmless resinous glaze per-

mitted under Section 402 (d) \* \* \* in terms of its ultimate constituents if it results in a statement meaningless to the purchaser. While it may, therefore, resolve itself into a question of fact in each case as to the most informative way of indicating this ingredient, we are disposed to feel that ordinarily it would be a substantial compliance with Section 403 (i) (2) to indicate the presence of harmless resinous glaze by the term 'resinous glaze'.

"So far as we are aware, carnauba wax is to be classed as a non-nutritive substance under the new Food, Drug, and Cosmetic Act, and since it is not included in the list of exempted non-nutritive articles in Section 402 (d) of the Act, it will not be a proper ingredient of confectionery under the new Act."

Correspondent asks whether it is permissible to coat confectionery with edible grades of stearic acid.



"The prohibition in Section 402 (d) of the Act against glaze in confectionery in excess of 0.4 per cent applies only to a non-nutritive substance. In the case of edible stearic acid, the 0.4 per cent limitation

would not apply, since it is not a resinous glaze nor is it non-nutritive. Its addition to confectionery would, however, be subject to the general provisions of the Act. \* \* \*

### "SILVER DRAGEES"—CONFECTIONERY

If Silver Dragees are sold exclusively for use in decorating cakes and are so used under conditions which preclude their consumption as confectionery, they would not be in the category of confectionery.

TC-239—April 11, 1940

Inquiry concerns small silver balls known as "Silver Dragees," which have been used by the bakery trade to decorate wedding and birthday cakes for many years.

"\* \* \* The specific prohibition in the Act against the presence of a nonnutritive substance is with respect to confectionery only.

"The Food, Drug, and Cosmetic Act does not define the word 'confectionery,' and that term is to be given its generally accepted meaning. There can be no question, therefore, but that if sold and used as confectionery these Silver Dragees are contraband under the Act. However, \* \* \* refers to their use in the bakery trade to decorate wedding and birthday cakes. There is no outright prohibition against the

presence of non-nutritive substances in the other food provisions of the law, the provisions of Section 402 (a) and (b) being, however, applicable in determining the legality of the addition of such substances in any case that might arise.

"If the Silver Dragees \* \* \* are sold exclusively for use in decorating cakes and are so used under conditions which preclude their consumption as confectionery, it is our conclusion that Silver Dragees used for that purpose alone would not be in the category of confectionery. In the absence of evidence of harm to health from the extremely small quantity of silver involved in the coating, we are not disposed to object to the presence of silver on these dragees when they are used as cake ornaments only."

### CONFECTIONERY—ASSORTED CHOCOLATES—LABELING

Letter discusses labeling of boxes of assorted chocolates. The top of the box is the main display panel on which mandatory information should be placed. The ingredient statement may begin on the main panel and continue down the side panel.

TC-240 (corrected)—April 25, 1940

Correspondent inquires about the declaration of the ingredients as required under Section 403 (i) (2) of the Act in the case of assorted candy in boxes, such as, for example, boxes containing individual pieces of "Maple Nut Creams," "Chocolate Cream Caramels," "Chocolate Nougats," and other items.

"While there is, of course, no objection to the listing of each of these items on the label, it is in our opinion necessary, in order to insure compliance with the requirements of Section 403 (i) (2), that the basic ingredients be listed, as for example, sugar, peanuts, chocolate, citric acid, dextrose, dried milk, or whatever different specific basic ingredients are present in the package. If some of these basic ingredients are not

common to all packages, the provision of Regulation 403 (i), Subparagraph (e) (2) is applicable. In indicating that other ingredients may be present, the statement should, in our opinion, be in terms of specific other ingredients which may be present rather than merely the label statement 'and other ingredients'. \* \* \*

"The first question you raise is whether the list of ingredients and other required information may be placed upon the bottom of the package provided a legible sticker is placed upon the front of the package showing that the information required by law will be found upon the bottom of the package. Section 403 (f) of the Act requires the ingredient list as well as the other mandatory information to be prominently placed on the label with such conspicuousness (as



compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Certainly, we feel that the bottom of the box cannot by any means be regarded as a prominent position for the mandatory label information, nor do we find any authority in the Act to hold that this failure to comply with Section 403 (f) can be corrected by a sticker on the top of the box directing the purchaser to look on the bottom.

"\* \* \* The mandatory information should preferably appear conspicuously on the top of the box. However, we do not believe the label will be misleading if the first line or two of the ingredient list appears prominently on the top and the remaining lines appear on the front of the box in a continuing label statement.

"Another question you raise is whether label declarations of artificial flavor or artificial color are required when only a few artificially flavored or colored pieces are present or when only a small quantity of artificial flavor or color is present. We call your attention to Section 403 (k), which classes a food as misbranded if it bears or contains *any* artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.

"You raise a question as to the position of the firm name and address on the package. Paragraph (a) (1) of the Regulation under Section 403 (f) makes it clear that a statement required under the Act may lack the required conspicuousness by failure to appear on the display panel. We have consistently advised inquirers to place the name and address in a prominent position on the top of the box to insure compliance with Section 403 (f)."

### CANDY—SODIUM BISULPHITE

Sodium bisulphite added to candy should be declared as an ingredient and as a chemical preservative.

TC-241 (See TC-317)—April 25, 1940

In response to an inquiry as to whether sodium bisulphite, when added to candy, may be declared on the label merely as a preservative or as sodium bisulphite, the following comment was offered:

"Section 403 (i) (2) and the corresponding regulation will, of course, require sodium bisulphite to be declared by its

specific name, since it is an ingredient of the candy to which it is added. Section 403 (k) will require sodium bisulphite to be declared as a chemical preservative. Therefore, in our opinion, to insure compliance with both of these sections, a proper form of declaration would be 'Preserved with Sodium Bisulphite' or 'Contains Sodium Bisulphite, a Chemical Preservative.'"

### CONFECTIONERY—CAKE DECORATIONS

The letter discusses the status of candle holders, birthday cake letters, and other cake decorations.

TC-242—April 25, 1940

Manufacturers of various cake decorations called at the Administration for the purpose of securing an interpretation of the provisions of the new Act as they may apply to their products.

"One type discussed was the usual candle holder made out of materials such as sugar and albumen and containing a metal wire for sticking the candle holder in the cake. The visitors were advised, as we have advised others, that provided the package in which these were sold did not refer to the material used in these candle holders as food or confection, and bore no suggestion that the material might be consumed, we

would not regard the item as a confection or food coming within the scope of the Food, Drug, and Cosmetic Act at all since its primary function was that of a candle holder and not a confection."

In a communication addressed to a manufacturer of similar products, the following comment was offered:

"\* \* \* We assume that the birthday cake letters consist of the same ingredients as the candle holders" (i.e., sugar, albumen, acetic acid, and artificial coloring). "If so, these cake letters, in our opinion, constitute confectionery under the Act and we would regard every cellophane-covered card bearing the letters forming the words, 'Happy



Birthday' as one retail package. Therefore, the mandatory label information required under Section 403 (e), (f), and (i) (2) should appear on the front of the card."

"\* \* \* The main difficulty arose with respect to the question as to how the quantity of contents should be declared on items of this character. They were finally advised that in our opinion, in view of the nature of the products and their intended use, we would not insist upon a net weight statement if the boxes in which the cards bear-

ing the cake decorations were enclosed bore some such statement as '1 complete cake decoration unit.' In some instances the cards on which the cake decorations were stuck were merely covered with cellophane and they were advised that in that case, if the number of units was less than six and the material was plainly visible through the cellophane, we would not require any quantity of contents statement."

### COSMETICS WITH PERFUME

The labels of cosmetics containing perfumes should differentiate between synthetic and natural perfumes.

TC-243—April 25, 1940

"It is our opinion that labels prepared for those cosmetics which are perfumed with material actually derived from flowers should not be identical with the labeling of cosmetics perfumed with synthetic odors. A construction of the application of the Food, Drug, and Cosmetic Act would, as you recognize, need to be based upon a knowl-

edge of whether or not consumers are misled by the label representations involved. It seems to us, however, that some such wording as 'Hair Lotion, Synthetic Rose Perfume' or 'Hair Lotion Perfumed with Synthetic Rose' would be the preferable form of labeling. The same principles would apply to perfume and toilet waters."

### PERFUMES—STATEMENT OF QUANTITY

Ordinarily a statement of contents of perfume in terms of the fluid dram is not informative. Bottles containing more than  $\frac{1}{8}$  fluidounce but less than one fluidounce of perfume should be designated in terms of the fraction of the fluidounce.

TC-244—April 25, 1940

"\* \* \* We now have sufficient evidence to show that ordinarily a statement of contents of the perfume in terms of the fluid dram is not informative. Paragraph (f) (1) under Section 602 (b) of the regulations provides that a statement of weight shall be in terms of the avoirdupois pound and

ounce, and a statement of liquid measure shall be in terms of the United States gallon, quart, pint, and fluidounce subdivisions thereof. It would therefore appear that bottles containing more than  $\frac{1}{8}$  fluidounce but less than one fluidounce of perfume should be designated in terms of the fraction of the fluidounce."

### CUTICLE REMOVER

Cuticle removers are regarded as cosmetics rather than as drugs.

TC-245—April 25, 1940

"You have inquired if an article intended for use as a cuticle remover is to be classified as a drug or as a cosmetic. While there have been no court decisions on this

subject, we are disposed to regard cuticle removers as subject to the cosmetic provisions of the Federal Food, Drug, and Cosmetic Act rather than to the drug provisions."

### CONFECTIONERY—RETAIL STORES

Containers of confectionery filled in retail stores at consumer's direction are not subject to the Act unless subsequently shipped interstate.



TC-246—April 25, 1940

"\* \* \* You advise that you are particularly concerned with the labeling information that must be placed on candy boxes which are filled in a retail store upon the direction of the consuming purchaser, who indicates the assortment which he desires packed therein.

"Under such circumstances, this Administration is disposed to regard the transaction

as local only and amenable to such provisions of state or local food laws as may be applicable. Of course, if in any case the package filled under such circumstances were to be shipped in interstate commerce by mail or otherwise, we can only point out that the labeling would have to comply in all respects with the Federal Food, Drug, and Cosmetic Act."

### CANNED FIELD CORN

There is no objection to the use of a subordinate explanatory statement on field corn labels reading "yellow variety" or "white variety." However, the possibility of consumer confusion with sweet corn is too great to sanction similar statement using word "golden" in any manner.

TC-247—April 25, 1940

In response to a telegraphic inquiry the following reply was made: "\* \* \* no objection use subordinate explanatory statement on field corn labels reading 'yellow

variety' or 'white variety.' However, possibility of consumer confusion with sweet corn too great to sanction similar statement using word 'golden' in any manner."

### "PEANUT BUTTER SANDWICH"

The ingredient statement of a "peanut butter sandwich" declaring merely the type of cracker used, instead of naming the ingredients of the cracker, is satisfactory.

TC-248—April 25, 1940

Visitor at interview submitted sketch of a new label for a peanut butter sandwich. The article will consist of peanut butter between two cheese-flavored crackers. The label bore the name of the article "Peanut Butter Sandwich" and underneath the ingredient statement in the following form: "Cheese Flavored Crackers and Peanut Butter". He wished to know whether this form of ingredient statement would be satisfactory in lieu of indicating the in-

gredients of the cracker, the composition of which he said he had no way of knowing.

"\* \* \* he was advised that the Administration would regard the declaration of the ingredients in the form which he had chosen as in satisfactory compliance with Section 403 (i) (2) of the new Act, provided, of course, evidence did not develop in the future to indicate that consumers were being denied information to which they were entitled."

### SHAMPOO TINTS—HAIR DYES

Shampoo tints are hair dyes within the meaning of the Act.

TC-249—April 25, 1940

"\* \* \* it is our opinion that shampoo tints are hair dyes within the meaning of the law. Such preparations, if subject to

Section 601 (a) of the statute, should be labeled according to the provisions of the Act applicable to coal-tar hair dyes. \* \* \*

### JURISDICTION OF ACT

Letter discusses the coverage of the Act in Hawaii, Philippine Islands, Puerto Rico, Virgin Islands, and the Canal Zone.

TC-250—April 25, 1940

"\* \* \* Since Hawaii is a Territory organized with a legislative body, distribution and sales of food and drugs, as well as

cosmetics and devices within the Territory of Hawaii do not constitute interstate commerce as you will note by Section 201 (b). Section 301 (g) does apply; in other words,



the Federal Act prohibits the *manufacture* within *any* territory of an adulterated or misbranded food, drug, device and cosmetic.

"There has, of course, been no judicial determination of the question which you raise concerning the application of the new law to the Philippine Islands. However, it is obvious from a consideration of Section 201 (b) of the Act that traffic within the Islands is not subject to the statute since the Philippines are organized with a legislative body. Furthermore, the Act of August 29, 1916, 39 Stat. 547, U.S.C. Title 48, Section 1003 provides that the statutory laws of the United States enacted subsequent to August 29, 1916 shall not apply to the Philippine Islands, except when they specifically so provide or it is so provided in the cited chapter.

"Administratively, it is to be anticipated that this Administration will regard pro-

ducts which have been manufactured in the United States and shipped to the Philippines as in essentially the same status as products exported to foreign countries and will be guided insofar as the section is applicable by the rules laid down in Section 801 (d) of the statute.

"Shipments of food, drugs, and cosmetics from the Continental United States to the Philippines, Puerto Rico, or the Virgin Islands are subject to the labeling and other provisions of the Act. In the case of Puerto Rico or the Virgin Islands, shipments to those territories would move in interstate commerce as that term is defined in the Act. \* \* \*

"Section 201 (a) exempts the Canal Zone only insofar as goods produced and sold wholly within that territory are concerned."

### COAL-TAR COLOR USED FOR THERAPEUTIC VALUE

A dye used for its therapeutic value and not for coloring purposes has the same status as any other drug product and is subject to all the provisions of the Act except those relating to the certification of colors.

TC-251—April 25, 1940

Correspondent inquires regarding the status under the Act of certain coal-tar derivatives.

"Section 504 provides for the listing and certification of coal-tar colors for use in drugs for coloring purposes only. Section 501 (a) (4) provides that a drug shall be deemed to be adulterated if it 'bears or con-

tains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 504.' You will note from this that a dye used for its therapeutic value and not for coloring purposes is placed in the same class as any other drug product and is subject to all the provisions of the Act except those relating to the certification of colors."

### CONTAINERS—"SHIPPING PACKAGE"

A package called a "shipping package," which may be used by the consignee for display purposes, should bear the information required to appear upon a label.

TC-252—April 25, 1940

In answer to an inquiry regarding the status of "shipping packages", the following opinion was expressed:

"He was told that if by 'shipping package' he refers to a package that may be used by the consignee for display purposes we think the information required by the

law to appear upon the label should appear upon such package. If, however, the 'shipping package' is merely a container for protection of the goods during transportation which will be discarded by the consignee upon receipt of the goods, we would not consider that it should necessarily carry the information required by the law to appear upon the label."



### COSMETIC CONTAINERS

The letter discusses the quantity of contents declaration in the case of small exempt units of the same article and of different type articles.

TC-253—April 25, 1940

Correspondent asks for information concerning the quantity of contents labeling of cosmetic containers, one of which contains three bottles of perfume, the other a box of face powder, a lipstick, and a bottle of perfume.

"You qualified your request by the statement that each unit is exempt by the regulations from the statement of the quantity of contents, but that the total content of each container would necessitate such statement. \* \* \* In the case of the first package, which contains the same type of article, \* \* \* we believe the container for the three bottles should bear on it the contents statement. \* \* \* we suggest the statement 'Contents: 3 bottles. Total volume—fluid ounce.' Either the decimal or the

common fraction may be used in revealing the quantity of contents. The decimal fraction should not, however, be carried out more than two places, and in case the common fraction is employed it should be reduced to such terms as are in customary use.

"Considering the fact that the other package contains different type articles, namely, face powder, lipstick, and perfume, we do not believe the quantity of contents statement is necessary provided each unit is so exempt by the regulations. In making this decision we reserve the right to make a change should it be found that the consumer is not obtaining all the protection to which he is entitled under the terms of the law, or should court decisions indicate a different policy."

### DISTRIBUTION BY COMPANY PURCHASING FROM SUBSIDIARY— USE OF TRADE NAME

The name of company which distributes products manufactured and sold to it by its wholly-owned subsidiary should appear on the label as distributor, not as manufacturer.

If an individual does business under a trade name, assuming full responsibility for its use, the use of such trade name is not objectionable.

TC-254—April 25, 1940

Correspondent's inquiry was based on the following set of circumstances:

ABC Manufacturing Corporation is a wholly owned subsidiary of ABC Corporation, each being incorporated in the same state. ABC Manufacturing Corporation actually manufactures and sells to ABC Corporation the products which ABC Corporation sells, in turn, to the retail trade. Both corporations have their principal offices at the same address and their officers and boards of directors are identical.

The question asked was:

"From the standpoint of Section 502 (a) and (b), may ABC Corporation place its name and address on the label of the products manufactured and sold to it by its wholly owned subsidiary, thereby indicating that it is the manufacturer?"

"\* \* \* since the ABC Manufacturing Corporation has an identity different from

that of the ABC Corporation, even though both corporations have their principal offices at the same address and their officers and boards of directors are identical, we are of the opinion that if the ABC Corporation's name appears upon packages of articles manufactured and sold to it by its wholly owned subsidiary, ABC Manufacturing Corporation, the label should indicate that the article is manufactured for or distributed by ABC Corporation. We think it would be improper to state under the circumstances outlined that the ABC Corporation is the manufacturer of the article."

"\* \* \* the label should state the name and place of business of the manufacturer, packer, or distributor. If an individual does business under a trade name, assuming full responsibility for the use of such trade name, our policy has been to hold that the use of such trade name is not objectionable."



**CANE AND MAPLE SYRUPS—BLENDS—INVERT SUGAR**

The letter discusses the labeling of cane and maple syrups blended in differing proportions.

If invert sugar is used, its presence must be declared on the label.

TC-255—April 25, 1940

Correspondent's inquiry concerns the labeling of "Cane and Maple Syrup," particularly with regard to what constitutes a substantial proportion of maple syrup in such a mixture.

"\* \* \* the Food, Drug, and Cosmetic Act does not require a statement of the percentage of each ingredient, but if the amount of any one ingredient in a mixture is such that failure to indicate, by percentage or otherwise, the amount present, deceives the purchaser, then of course a percentage statement would be an obvious method of correcting the deception.

"If maple syrup is present in the mixture about which you are concerned in substantial amounts, we do not regard it as necessary that it be declared in terms of percentage. \* \* \*

"In order to insure that you are in compliance with the labeling requirements, we renew our suggestion that the percentage of maple syrup be declared on the label if less than about 25 per cent. Thus, if the mixture contains more than this percentage of

maple syrup, we believe the name 'Cane Sugar and Maple Syrup' will satisfy the requirements with respect to the listing of ingredients. If the percentage of maple syrup is between about 10 and 25 per cent, we believe the name 'Cane Sugar and Maple Syrup' qualified by the prominent statement 'Contains — per cent Maple Syrup' would be suitable. If the percentage of maple syrup is insignificant, i.e., less than about 10 per cent, we believe the name 'Cane Sugar and Maple Syrup,' even if accompanied by the qualified legend regarding the percentage of maple syrup, would not be appropriate since the product would, in our opinion, no longer be a cane sugar and maple syrup but a sugar syrup with a slight addition of maple syrup, and a more appropriate label would be 'Sugar Syrup with a trace of Maple Syrup Added.'

"In your letter you also advise that you have been using a small amount of invert sugar in addition to the cane sugar and maple sugar in preparing your blend. If you do add invert sugar, then it will be necessary that its presence also be stated on the label."

---

**CRABMEAT—ADDED SALT AND CITRIC ACID**

Administration is not disposed to require label declaration of added salt or citric acid if the crabmeat is thoroughly drained after dipping in acidified brine, and the salt and citric acid are not added directly to the canned product as constituents of a packing medium.

TC-256—April 25, 1940

"This Administration has conducted no experimental work on the canning of crabmeat and we cannot advise you as to whether or not the pre-treatment method of dipping the crabmeat in acidified brine, which you describe, will suit your purposes. In any event, we have no authority actually to approve processes. The most we can say in this connection is that we are aware that technologists who have studied methods of crabmeat canning have recommended dipping the meat in brine containing citric

acid in order to prevent discoloration during subsequent processing, and that we see no objection to the procedure. On the assumption that following immersion in the acidified brine the crabmeat is to be thoroughly drained and that salt and citric acid are not added directly to the canned product as constituents of a packing medium, in other words, that the product is 'dry packed,' we are not disposed to require that the labels bear a statement of added salt or citric acid."

---



## CONFECTIONERY—CANDY SOLD BY PIECE

Candy sold individually, by the piece or as so-called "penny goods," need not be labeled. If the wrapper is printed by the manufacturer, however, so as to constitute a label, complete labeling is necessary.

TC-257—April 25, 1940

"\* \* \* In the case of penny goods, the Administration is not disposed to regard it necessary to label each individual piece with mandatory label information required by the new Act, but where the manufacturer himself elects to use the wrapper as a label by putting any statements on it we hold that the wrapper should then bear the firm name and address, a list of the ingredients, and the net weight. You therefore have the alternative of using plain unlettered wraps or of adding the net weight statement and

an ingredient list to the present label statements. \* \* \*

"We are not inclined to regard the printed initials 'B' or 'K' on cellophane wraps for individual hard candy balls sold by the piece as evidence of an intention on the part of the manufacturer to make a label of the cellophane wraps, provided the initials alone are present and they have no misleading significance. Consequently, we would not, under these conditions, insist that the wraps bear the information required by the new \* \* \* Act for labels."

## FISH—FISH FILLETS

The letter discusses the labeling of fish and fresh and frozen fish fillets.

TC-258—April 25, 1940

Correspondent inquired whether objection would be raised to the designating of fish fillets produced from whiting (silver hake) by brand names which would partly but not entirely reveal the species of the fish.

"\* \* \* Your attention is directed to Section 403, which deals with the misbranding of food, and particularly to paragraph (i) clause (1) which states that food for which no standard of identity has been promulgated shall be deemed to be misbranded unless its label bears the common or usual name of the food, if any there be. In this case the common or usual name of the fish is 'whiting,' or 'silver hake,' and in accordance with the provisions of the law fillets prepared from such fish must be so labeled, regardless of the brand name that may be used. We see no objection to the use of the designations given in your letter as brand names on labels for whiting fillets with the reservation, of course, that fish labeled as 'Cape Cod fillets' must be produced in that geographical area, provided the labels also bear a plain and conspicuous declaration that the fish is whiting, or silver hake. We can not view the proposed designations as acceptable substitutes for the common or usual names for this species of fish."

Correspondent submitted a cellophane wrapper to be used on frozen fish, the wrapper bearing the brand name, the common name of the article, and the name and address of the distributor. The question

was asked as to whether fish so wrapped would be considered in package form.

"However, while we are inclined to regard frozen fish wrapped in cellophane wrappers such as you submit as in package form, we are not inclined to insist upon a statement of the net weight on each individual wrapped piece where there is a variation between pieces, provided the box or other outer container holding several of these wrapped pieces does bear a correct statement of the net weight of the total amount of fish in the box, and further provided the individual fish when sold to the ultimate purchaser is weighed and sold by weight.

"You first ask whether, if the boxes or cartons are properly labeled, the individual fresh or frozen fillets may be wrapped in unprinted wrappers. In our letter to you \* \* \* we discussed this question so far as it applied to the net weight statement and pointed out that, in the case of fillets which vary materially in weight and which are invariably weighed at the time of sale, we are not intending to institute action against such wrapped fillets solely because of the absence of the net weight statement on the individual wrapper, provided the fifteen-pound boxes in which the fillets are shipped to the dealer bear the net weight on such boxes and the other required label information. We reaffirm that statement in regard to the net weight, but we are not prepared to give you any assurance at this time that the individual wrappers could be regarded as legal if they fail to bear the name of the



fish and the name and address of the packer or distributor, even though this information appears on the boxes or cartons.

"You also ask whether when the species of fish is printed on the wrapper the latter must also state whether the product is fresh or frozen.

"If the product is in fact frozen fillets, we believe the fact that the article is frozen should be stated on the wrapper, since the

wrapped fillet may be sold to the ultimate consumer after thawing, when its physical condition no longer apprises the purchaser that it has been subjected to a freezing process. Fresh fillets which are sold without intervention of a freezing process can, of course, be appropriately labeled as 'fresh' although this is not essential. The term 'frozen fish' is regarded as suitable for fresh fillets which have been promptly subjected to a freezing process."

### "CHOCOLATE ICE CREAM"

Pending the promulgation of standards of identity for ice cream, the Administration will not institute action where cocoa is substituted for chocolate in flavoring "Chocolate ice cream."

TC-259—April 25, 1940

Correspondent inquires whether it is not improper under the new Act to label ice cream sold within its jurisdiction as "Chocolate" unless chocolate is used in its preparation. In reply, his attention was called to the Department's letter of May 4, 1939, (TC-64), temporarily exempting ice cream and other named frozen desserts from the ingredient labeling provisions in Section 403 (i) (2), and he was further advised as follows:

"Obviously definite advice as to specific labeling can hardly be given for ice cream and frozen products until the final definition and standard of identity is adopted. We can only say in the meantime that it is not the purpose of this Administration to institute action where cocoa is substituted in whole or in part for chocolate in flavoring 'chocolate ice cream.'"

### DENTAL SUPPLIES—CLASSIFICATION

Supplies which enter into the materials used in filling teeth and in making dentures are either devices, accessories to devices, or drugs, depending upon the representations made.

Material used to take impressions is not a device, but a dental plate is.

A product intended to hold artificial teeth in place is an accessory for a device and subject to the Act.

TC-260—April 25, 1940

"It is our opinion that all supplies that enter into the materials used in filling teeth and in making dentures are either devices, accessories to devices, or drugs, depending upon the representations for the specific article, and are therefore subject to the provisions of the Food, Drug, and Cosmetic Act.

"\* \* \* It is our opinion that material used to take impressions is not a device as this term is defined in the Act and is not subject to the provisions of the Act. The

dental plates themselves are obviously a device and must comply with the provisions of Chapter V. \* \* \*

"The definition of the term 'device' in the Act includes accessories for any article intended to affect the structure or any function of the body of man or other animals. It is our opinion that a product intended to hold artificial teeth in place is an accessory for a device affecting a function of the body and is therefore subject to the provisions of the Act."



**CARBONATED WATER—MINERAL SALTS—"CLUB SODA"**

Pending the promulgation of standards for sodas and soda water, no objection will be made to designating a club soda consisting of carbonated water with a small amount of "alkalinity" and mineral salts as "Club Soda," followed by appropriate ingredient labeling.

TC-261—May 7, 1940

Correspondent inquires regarding the labeling of a club soda consisting of carbonated water containing a small amount of "alkalinity" and mineral salts.

"The name 'Club Soda' is applied in the beverage industry both to flavored and unflavored carbonated beverages. Some of the beverages labeled with this name are ordinary lemon or lime sodas or soda waters. Others, such as the one to which you refer, are merely carbonated water with the addition of a small amount of mineral salts.

"Pending the promulgation and effective application of standards for sodas and soda

water, no objection will be made to designating your product as 'Club Soda' followed by appropriate ingredient labeling such as 'Carbonated water' followed by the names of the individual mineral salts in the order of predominance. We do not consider that carbonated water with a small amount of added mineral salts is included in the exemption from ingredient labeling which, as you no doubt know, has been granted to carbonated beverages, as such a product is in the nature of a carbonated artificial mineral water which has always been regarded as being in a different category from bottled soft drinks, to which the exemption applies."

**BEVERAGE BASE—"CONCENTRATED ORANGE JUICE"**

The name "Concentrated Orange Juice" is applicable only to orange juice free from excess orange oil, which has been subjected to concentration with the aid of heat.

TC-262—May 7, 1940

Correspondent requests advice as to the propriety of the proposal to change the name "\*\*\*. \*\*\* Orange Concentrate" to "\*\*\*. \*\*\* Concentrated Orange Juice" on the label of a product which consists of concentrated orange juice, sugar, and a small amount of concentrated lemon juice.

"In our opinion, the name 'Concentrated Orange Juice' is applicable only to orange

juice free from excess orange oil, which has been subjected to concentration with the aid of heat. This name should not be applied to a mixture of concentrated orange juice, sugar, and concentrated lemon juice.

"\*\*\* this product appears to be a beverage base and should be designated as such or by a name which is equally informative and truthful."

**CANNED FOODS—MIXTURE OF TWO STANDARDIZED VEGETABLES**

A mixture of two canned standardized vegetables, such as carrots and peas, would be appropriately designated as "Carrots and Peas" or "Peas and Carrots," depending on which vegetable predominates.

TC-263—May 7, 1940

Correspondent requests information as to the labeling of a mixture of canned carrots and peas.

"As you know, a definition and standard of identity has been promulgated for canned carrots and also for canned peas. The mixed product you have in mind would be a mixture of two standardized

vegetables and, in our opinion, would be appropriately designated on the label as 'Carrots and Peas' or 'Peas and Carrots,' depending upon which vegetable predominated.

"Our present interpretation is that it is not necessary in such an unstandardized mixture to state on the label, for example, 'Diced Carrots and Alaska Peas.'"



### SYRUPS—"ROCK CANDY SYRUP"

The labeling of a partially inverted sugar cane syrup should contain a statement such as "Partially Inverted" appearing in conjunction with the name "Sugar Cane Syrup."

The term "Rock Candy Syrup" should be strictly applied.

TC-264—May 7, 1940

Correspondent's inquiry relates to the labeling of a partially inverted sugar cane syrup.

"We are of the opinion that a statement such as 'Partially inverted' should appear in conjunction with the name 'Sugar Cane Syrup.' \* \* \*

"\* \* \* We think the designation 'Rock Candy Sirup' on a label for mixed table

sirup would definitely imply that that ingredient was the sirup remaining after crystallization of 'rock candy.' Even though rock candy sirup and sirup made from what you term 'confectioners A sugar' may be of essentially the same identity, we cannot escape the conclusion that in order to avoid any possibility of misleading the purchaser, the term 'rock candy sirup' should be used exclusively for the article generally known under that name."

### CANNED PEAS—ARTIFICIAL COLOR

The letter discusses labeling requirements when artificial color is used in canned peas.

TC-265—May 7, 1940

"\* \* \* The standard of identity for canned peas (Federal Register for February 24, 1940) provides for the optional ingredient 'Artificial Coloring,' but only in those instances in which color is used without concealing damage or inferiority or making the product appear better or of greater value than it is. If this firm's peas come within this category, subsection (c) of the quality standard requires them to be labeled either 'Below Standard in Quality Good Food—Not High Grade,' as provided in Section 10.020 (a) (Federal Register for July 18, 1939), or 'Below Standard in

Quality Artificially Colored,' as provided in Section 51.001 (c) (2) (Federal Register for February 24, 1940). If the first optional form of statement is used, Section 403 (k) of the Act requires that the label also bear the statement 'Artificially Colored.' \* \* \*

"\* \* \* We now interpret Section 51.001 (c) (2) to mean that the option is merely with respect to the wording and not with respect to the other requirements of Section 10.020 (a). Therefore, the optional form of statement should be enclosed in the box and should be of the size and style of type prescribed by Section 10.020 (a)."

### OYSTERS—USE OF TAG FOR MANDATORY LABELING

The letter discusses the use of a tag to contain the information required by the Act with respect to shipments of oysters, shucked and shell stock.

TC-266—May 7, 1940

"You refer to the packing of fresh shucked oysters in cans, several cans being packed in iced containers. These oysters are sold to wholesale and retail dealers who in turn sell the cans in less than package lots. You advise that at present such containers (the cans) bear a label or tag showing the permit number of the producer, prefixed with the State initials, his name and address, and other information permitting the tracing of the oysters to the beds from which they came. The net contents statement is stamped into the metal of the can,

that is, 'one gallon.' You ask whether the present method of using tags attached to the containers, which contain the required information, will meet the requirements of the law or whether this information must appear on the can itself.

"The Act does not necessarily require this information to be placed upon the can itself. If the information required by Section 403 of the Act appears upon a tag securely affixed to the container and the tag and its information are sufficiently conspicuous to conform to the requirements of Section 403 (f), the continuance of the



practice of using tags would appear to meet the requirements of the Federal Act.

"You refer to oysters in the shell packed in barrels, bags, or boxes and sold in the same channels of trade as shucked oysters. You advise that these packages when shipped have attached to them tags bearing the required label information, and you ask whether this method of tagging complies

with the law.

"Essentially the same answer can be made in this case as in the case of fresh shucked oysters. The criterion is whether or not the method of presenting the required information on the tags fulfills the provisions of Section 403 (f) as to conspicuousness."

## DRUGS—LABELING OF DERIVATIVES

A statement that an ingredient is a derivative of a substance required by the Act to be declared need not appear separately on the label if the name of the ingredient in itself reveals this fact.

TC-267—May 7, 1940

"In reply to your letter \* \* \* with reference to the labeling of derivatives of narcotics and hypnotics, in our opinion it will not be necessary to add to the declaration 'Morphine Sulfate' a parenthetical statement 'Morphine Derivative' since the name 'Morphine Sulfate' shows that the substance is derived from morphine. The same reasoning applies to the declaration of codeine sulfate.

"\* \* \* we are of the opinion that if the name 'sodium cacodylate' appearing upon a label in connection with the declaration of the quantity or proportion of an arsenic derivative in a medicinal preparation is accompanied by the parenthetical statement

to the effect that this is sodium dimethylarsenate, it will not be necessary to add that this is a derivative of arsenic, since the term 'dimethylarsenate' itself shows that the article is a derivative of arsenic.

"\* \* \* In the case of iron cacodylate it will be necessary to declare the amount of this substance present in the preparation and to indicate that it is an arsenic derivative.\* \* \*

"It is our opinion that such names as 'strychnine sulfate' and 'ammoniated mercury' in themselves indicate that the compounds are derivatives of strychnine and mercury and that no further derivative statements are required."

## DRUG NOMENCLATURE

If the identity of a drug differs from that prescribed by an official compendium, the drug may not be legally designated by the title recognized in the compendium with a qualifying phrase.

TC-268—May 7, 1940

"The Food, Drug, and Cosmetic Act provides for the distribution of articles sold under official names which vary in strength, quality, or purity from the official articles. The Act does not provide for any change in the identity of the ingredients. It is our opinion that an ointment consisting of 20 per cent zinc oxide and petrolatum cannot legally be sold as Zinc Oxide Ointment with any qualifying phrase.

"You have submitted a label for a product designated 'Elixir Aminopyrine Not N. F.

VI,' and the statement that 'This preparation differs from the N. F. VI formula in the aromatic vehicle base and color'. We refer you to Section 501 (b) of the Act and to the regulations covering this section. Since the statements on the label indicate that your preparation is not the official article recognized in N. F. VI as to the identical ingredients contained in the official preparation, the law does not permit distribution of your article within its jurisdiction under the designation of 'Elixir Aminopyrine.'"



**MEDICINAL SOAP**

The quantity of contents of medicinal soap should be expressed by weight rather than by numerical count.

TC-269—May 7, 1940

"You have asked if it will not be possible to designate medicinal soap by numerical count rather than by weight since soap is subject to changes in weight due to loss of moisture content. It is our opinion that the labels of soaps which are subject to the

provisions of the Act must bear a statement of the weight of the soap. In connection with the variation due to the loss in moisture, your attention is called to Regulation (k) (1) under Section 502 (b).

\* \* \*

---

**NUX VOMICA—STRYCHNINE**

While a nonofficial drug which contains nux vomica as an active ingredient is required so to state upon the label, that statement does not relieve the manufacturer of the necessity of declaring the quantity or proportion of strychnine, one of the constituents of nux vomica.

TC-270 (reissued)—August 20, 1940

(Explanatory note: As issued on May 7, 1940, TC-270 was based upon an Administration opinion written prior to the change of wording in the general regulation under Section 502 (e) of the Act. Consequently the wording quoted from paragraph (a) (1) of the regulations does not agree with the wording of the amended regulation under this section. For the purpose of correcting TC-270, an opinion currently rendered on this subject would read as follows:)

"The Act requires a declaration of each active ingredient including the quantity of strychnine or any derivative or preparation of it which is contained in a nonofficial drug preparation. As used in the Act, it is obvious that the term 'ingredient' refers to a substance used in the fabrication of a drug. In the section under consideration the phraseology used is 'in case it is fabri-

cated from two or more ingredients.' In this sense strychnine is not an 'ingredient' of nux vomica although it is a constituent of that drug. To regard strychnine as an ingredient of nux vomica would, if we were to be consistent, require that the numerous constituents of every nonofficial plant drug which might be regarded as active be stated on the label. In many instances the identity of such constituents is not known. We cannot think that Congress intended to make any such requirement. What was obviously intended was that the label bear the name of the crude drug itself where that drug is an ingredient of a preparation. While, therefore, a nonofficial drug which contains nux vomica as an active ingredient is required to so state upon the label, that statement does not relieve the manufacturer of the necessity of declaring the quantity or proportion of strychnine, one of the constituents of nux vomica."

---

**RAW SUGAR**

The letter discusses the status of raw sugar.

TC-271—May 7, 1940

Correspondent inquires about the status, under the Food, Drug, and Cosmetic Act, of raw sugar.

"This is the term generally applied to the intermediate food product as it leaves the sugar factory for further refinement in sugar refineries before use as food. In general, raw sugar is unsuitable for food because it contains extraneous impurities which are completely removed in the refining process. The Food, Drug, and Cosmetic Act does not prohibit outright the

shipment of raw sugar. However, we have had occasion to institute action against raw sugar intended for food use without further refinement which was found to contain impurities rendering it unsuitable for food use. If wholesalers and retailers have calls for raw sugar for food use direct, it is incumbent upon them to assure themselves that the particular raw sugar they sell for that purpose is free from filth, dirt, and decomposition. We know of no process for freeing raw sugar of such impurities short of the usual refining process of sugar refiners."



## SALT

Salt used by textile mills, ice companies, or concerns where it is not intended for human or animal consumption is food under the Act. Administration does not intend to regulate traffic in salt shipped for such purposes.

TC-272—May 7, 1940

Correspondent states his understanding that salt used by textile mills, ice companies, or concerns where the salt is not intended for human or animal consumption is not covered by the Food, Drug, and Cosmetic Act.

"We cannot escape the conclusion that the literal interpretation of the term 'food' as defined in Section 201 (f) of the Act includes salt for whatever purpose it may be intended in specific instances. However, it is not our purpose to deviate from more important regulatory problems to the regulation of traffic in salt shipped for the purposes you mention, provided it is shipped in such channels and under such circumstances as obviate in any

case its diversion for food or feed purposes.

"You also state \* \* \* your understanding that it is necessary that salt be in labeled packages when it is shipped for human or animal consumption even though shipped to a customer who is a direct consumer and the salt is not offered for resale. You are correct in your understanding.

"You inquire also as to the attitude of the Department as to salt shipped in bulk or loose in car. Salt intended for food or animal feeding purposes, shipped in bulk or loose in car, is amenable to all of the applicable provisions of the Food, Drug, and Cosmetic Act although it is, of course, not food in package form."

---

BLENDING EDIBLE OILS—LABELING

The letter discusses the labeling required for cans of blended edible oils.

A product containing but one ingredient is not entitled to exemption from Section 403 (i) (2).

TC-273—May 7, 1940

Correspondent requests advice as to the labeling required for cans of blended edible oils.

"We enclose a copy of the new Act and general regulations. Your attention is called to Section 403 (e), (f), and (i) (2). As you indicate, the firm name and address should be prominently set forth on each main display panel of the label, together with the net contents statement and the list of ingredients. \* \* \* The specific oils should be listed on the label in the descending order of predominance by weight. If in any case, one oil, such as olive oil, is present in relatively small amounts, we believe that, in order to insure compliance with the Act, it will be necessary to indicate the percentage of that particular oil. For example, instead of 'Flavored with Olive Oil,' as suggested by you, we believe the statement should be 'Flavored with — per cent Olive Oil' in the case of a mixture containing a small amount of olive oil."

Correspondent submitted specimen lithographed can for "\* \* \* Oil for Salads & Cooking 1 Pint Net Made from Golden Corn" and requested an exemption from Section 403 (i) as provided for in Section 902 (a) (2) of the Act.

"You will note that the power of exemption provided for in Section 902 is limited to cases of foods fabricated from two or more ingredients, and we understand that your product consists solely of corn oil. The requirements of Section 403 (i) and Section 403 (f) of the Act will, therefore, make it necessary that the label be revised so that the common or usual name 'Corn Oil' is set forth on the label with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. We do not feel that the running statement 'Made from Golden Corn' satisfies the requirement as to the common or usual name of the article. \* \* \*"

---



## CONTAINERS FOR FRESH FRUITS AND VEGETABLES

The Administration will not institute action against fruits and vegetables in open containers between one quart and four quarts in capacity for failure to be labeled with quantity of contents and other mandatory information, provided they are in even multiples of one quart.

TC-274—May 7, 1940

Correspondent inquires in regard to a regulation concerning fruit baskets containing over one quart.

"I think no doubt what you refer to is Subparagraph (a) (2) of the regulation under Section 405 of the Food, Drug, and Cosmetic Act. This regulation was promulgated under authority of Section 405 (1) of the new Act, which \* \* \* gives the Secretary authority to exempt from any labeling requirement of the Act 'small open containers of fresh fruits and fresh vegetables.' In promulgating this regulation the Secretary had for determination the question of the dividing line between a small open container and a large one. This regulation sets one quart as the upper limit of 'small' in the case of open containers of fresh fruits and fresh vegetables. One quart was fixed in the regulation exempting small containers primarily because of a court decision under the Standard Container Act, which

held its provisions do not apply to small containers of tree fruits or grapes. As a consequence of that decision odd-sized containers appeared, such as for example  $1\frac{1}{3}$  quarts,  $1\frac{5}{6}$  quarts,  $2\frac{1}{2}$  quarts, etc. Since the public has learned to expect sizes of so-called 'till' baskets to be in even multiples of quarts, the failure to declare the quantity of contents on these odd-sized containers would not, of course, give adequate information to the purchaser.

"While the regulation under Section 405 does fix one quart as the upper limit of 'small containers,' the Department will not institute action against fruits and vegetables in open containers between one quart and four quarts in capacity for failure to be labeled with the quantity of contents and other mandatory label information, provided they are in even multiples of one quart, that is, two quarts, three quarts, and four quarts."

## VANILLA AND VANILLIN FLAVORING MIXTURES— "IMITATION VANILLA FLAVOR"

Unless vanilla contributes at least 5 per cent of total flavor of product entitled "An Imitation Vanilla Flavor," vanilla should not be listed as an ingredient without qualification. Food products flavored with mixture of vanilla and vanillin flavors should be labeled to show they are flavored with both.

If "Vanilla wafers" contain a significant amount of vanilla flavor, it may be listed as a flavoring ingredient. Unless the vanilla contributes at least 5 per cent of the total flavor, it should not be listed without some qualifying expression.

TC-275—May 7, 1940

"Not being advised of the quantitative manufacturing formula of \* \* \* 'An Imitation Vanilla Flavor,' the label of which lists vanilla as an ingredient, we cannot advise you as to whether it would be necessary to qualify the word 'Vanilla' in the list of ingredients by some such statement as 'A Trace of Vanilla.' We are of the opinion that unless vanilla contributes at least 5 per cent of the total flavor of the mixture, vanilla should not be listed as an ingredient of an imitation vanilla flavor without qualification.

"One of the labels for your 'An Imitation Vanilla Flavor' lists 'Aromatics' as an ingredient. We believe that the label should be more specific with regard to the kind of aromatics used."

Correspondent inquires whether the name "Vanilla Wafers" is a proper one for wafers flavored with a combination of artificial and true vanilla flavor.

"You will note from page 4 of the enclosed mimeographed article 'Flavoring Extracts'" (TC-12) "that a flavor consisting of a mixture of vanilla and vanillin flavors is not 'Vanilla Flavor' but is 'Vanilla and Vanillin Flavor,' provided the vanilla ingredient contributes approximately as much flavor as the vanillin. It follows that food products flavored with such a mixture should be labeled to show that they are flavored with vanilla and vanillin and not merely with vanilla. Moreover, Section 403 (k) requires that food containing any



artificial flavoring shall bear labeling stating that fact. Vanillin is of course an artificial flavor.

"In the light of the above comments, appropriate labeling for your wafers would be 'Wafers,' followed by the words 'Artificially flavored with vanillin.' If your wafers contain a significant amount of true

vanilla flavor, there will of course be no objection to listing vanilla as a flavoring ingredient on the label also. However, unless the true vanilla contributes at least 5 per cent of the total flavor, we do not believe it should be listed on the label without some qualifying expression such as 'A trace of vanilla flavor.' \* \* \*

### PROCESS CHEESE

The temporary exemption with respect to "straight" or unmixed cheese does not include process cheese. Until standards for process cheese are promulgated, process cheese should conform to advisory standard promulgated under Food and Drugs Act of 1906 and be labeled with a statement of the ingredients.

TC-276 (Rescinded, See TC-341)  
May 7, 1940

"The Secretary's exemption in this case refers to 'straight' or unmixed cheese and does not include process cheese. For this reason, the exemption from labeling with a statement of the ingredients which are used in manufacturing does not apply to process cheese \* \* \*.

"\* \* \* Until such time as standards for process cheeses under the new law are promulgated, we are guided in our determination of what constitutes process cheese by the advisory definition and standard of identity for process cheese promulgated under the old Food and Drugs Act. \* \* \*

"Therefore, process cheese should con-

form in composition to the old standard and should be labeled with a statement of the ingredients. In addition, of course, the label should carry the common or usual name 'Process Cheese' qualified by the proper varietal designation. With American or Cheddar process cheese the qualifying varietal name is not required since the unqualified words 'Process Cheese' are understood to mean American (or Cheddar) Process Cheese. The label should also bear the net weight and the name and address of the manufacturer, packer, or distributor. All of the required information should be conspicuously set forth on the label.

"\* \* \* If any water is used in the process, water should also be declared as a constituent.\* \* \*

### MUNSTER AND TILSIT CHEESES IN PLAIN WRAPPERS—SWISS CHEESE IN TUBS

If Munster and Tilsit loaves of cheese are placed in plain waxed paper, for the purpose of protecting them against abrasion during shipment, and the wrappers are removed when cheeses are exposed for sale, the articles will not be considered to be food in package form.

Swiss cheese in tubs constitutes food in package form, and should bear the statements required by Section 403 (e).

TC-277—May 7, 1940

"\* \* \* if the Munster and Tilsit loaves of cheese are placed in plain waxed paper, simply for the purpose of protecting them against abrasion during shipment, and these wrappers are removed when the cheeses are exposed for sale, we would not consider the articles to be food in package form. If, however, such individual cheeses are securely wrapped in the waxed papers and these are not removed from the cheeses when exposed for sale, we would consider them to be food in package form and sub-

ject to the mandatory labeling requirements under the Food, Drug, and Cosmetic Act."

Correspondent inquires whether Swiss cheeses, manufactured in loaf form and packed several loaves in a large shipping container, would be required to be labeled in accord with Section 403 (e) of the Act.

"You express the opinion that this is bulk merchandise which does not come within the purview of the Act. Under the provisions of the Food and Drugs Act of 1906, a tentative conclusion was reached a number of years ago that Swiss cheese in loaves



weighing approximately 100 pounds each, and packed in tubs, usually four loaves to the tub, was not food in package form requiring a net weight declaration. This interpretation exempting tubs of Swiss cheese from the quantity of contents statement, if applied to the language of the new food law, would, in effect, extend the exemption to the other mandatory requirements for food in package form. It is quite evident that in the case of the new law Congress

has specifically indicated in Section 405 (2) the conditions under which a food may not be required to bear the mandatory labeling statements. It is our opinion that under the new law Swiss cheese in tubs constitutes food in package form and should bear the required statements of Section 403 (e), namely, the quantity of contents statement and the name and address of the manufacturer, packer, or distributor, as the case may be."

### CANNED DOG FOOD

There will be no objection to the designation "meat by-products" in ingredient list of canned dog food in lieu of declaring each by-product.

TC-278—May 7, 1940

Correspondent's letter has reference to the declaration of meat by-products on the labeling of canned dog food.

"\* \* \* we have had occasion to give more extended consideration to the question as to the practicability of declaring each individual constituent and, in the light of

information comparable to that presented by you, we will not, for the time being at least, object to the designation 'meat by-products' in lieu of declaring each by-product ingredient, provided, of course, the by-products used are sound and wholesome and are limited to those articles which are legitimately referred to as 'meat by-products.'"

### COTTAGE CHEESE—"CREAMED COTTAGE CHEESE"

Cottage cheese in tubs is food in package form. The product is included in the temporary exemption from ingredient declaration.

When cream is added to cottage cheese, the designations "Cottage Cheese With Cream Added" and "Cottage Cheese and Cream" are preferred to "Creamed Cottage Cheese."

TC-279—May 7, 1940

"Cottage cheese shipped in tubs or tins and farmer cheese shipped in wooden cases would be regarded as food in package form and required \* \* \* to bear the name and address of the manufacturer, packer, or distributor, and a statement of the weight of the cheese in the package. This can be done by paper stickers, in a plain and conspicuous manner, or by means of tags attached to the container whereon the information is printed plainly and conspicuously. In addition to this information, the label should also bear the common or usual name of the product. The new law provides that foods containing two or more ingredients bear also a list of the ingredients as provided in Section 403 (i) (2). Under the authority of Section 902 (a) (2) normal cheeses have been exempted from the requirement of listing the ingredients pending the formulation of standards. Cottage

cheese or farmer cheese consisting solely of curd and salt could be designated as 'cottage cheese' or 'farmer cheese' without a list of the ingredients. However, in cases where cream is added, a label statement to this effect should be made, and where spices or flavoring are added, the label should bear the word 'spices' or 'flavoring,' in keeping with fact.

"In discussing the appropriateness of the designation 'Creamed Cottage Cheese' \* \* \* was advised that there is some question as to the meaning of the term 'creamed cottage cheese' to the consumer and possibility of confusion with cream cheese; that we therefore prefer to have the product designated as 'cottage cheese with cream added' or 'cottage cheese and cream'. It was pointed out that such a designation would also serve as a statement of ingredients. \* \* \*"







**HEXAMETHYLENETETRAMINE—COD FISH CAVIAR**

Hexamethylenetetramine cannot be sanctioned for use as a preservative in cod fish caviar.

TC-284—May 7, 1940

Correspondent inquires about the permissibility of the addition of hexamethylenetetramine in quantities as small as 15/100 of one per cent to codfish caviar.

"It is our understanding that when hexamethylenetetramine is added to fish spawn that has been fermented, the antifermenta-

tion action of the compound rests on its ability to liberate formaldehyde in the acid medium. Formaldehyde has never been permitted as a preservative in foods and we are not, therefore, in position to sanction the use of hexamethylenetetramine for the purpose you have in mind."

---

**IMITATION FLAVORS**

If synthetic esters, ketones, and aldehydes are grouped in ingredient statements under these group names, one member of each group should be specifically named, as "Amyl acetate and other esters."

TC-285—May 7, 1940

Correspondent submits proposed wording for an ingredient statement to appear as a supplemental sticker on labels for imitation flavors and essential oil emulsions, the statement to read as follows: "This flavor contains some of the following material: Alcohols, aldehydes, ethers, esters, ketones, lactones, essential oils, edible vegetable oils, methyl and ethyl vanillin, coumarin, sugar, glycerin, water, artificial color."

"\* \* \* the ingredient labeling you propose to use on the sticker will not meet

the requirements of the Act, since the purchaser will not be advised as to the composition of the particular product he is buying. The list of ingredients should show what is contained in each product and if group names such as aldehydes, esters, and ketones are used, we have advised correspondents that at least one member of each group should be specifically named, as for example, 'Benzaldehyde and other aldehydes,' 'Ethyl acetate and other esters,' etc. The particular vegetable oil that you use should be specifically named. \* \* \*"

---

**CHOPPED FISH IN SAUSAGE CASING**

Chopped fish packed in sausage casing should not be designated as "sausage."

TC-286—May 7, 1940

Correspondent requests advice on the labeling of a fish product packed in sausage casing, similar to meat sausage except that it consists of chopped fish. \* \* \*

"On a product that has the appearance and general characteristics of the customary sausage we believe the labeling should very specifically advise the consumer that the

product is not the article generally expected as one composed of meat ingredients. In this connection the courts have ruled that the name 'sausage' would be inappropriate on articles other than those conforming to the generally accepted identity of sausage. We believe that in the choice of a name for the product your client should be guided by this opinion."

---

**MINERAL OIL—RUSSIA**

Mineral oil obtained from sources outside the Russias and labeled as "Russian" or "Russian type" is violative of the Act.

TC-287—May 7, 1940

"One of the provisions of the Act is that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular (Section 502 (a)). It is our

opinion that white mineral oil obtained from sources outside the Russias and labeled as 'Russian' or 'Russian type' is violative of this section of the Act if marketed within its jurisdiction."



**FEED—LABELING ON SACK AND TAG**

Under the circumstances, no objection will be offered if the necessary information would be contributed to the buyer without requiring all of the list of ingredients to appear on the face of the sack of feed, provided that what appears on the attached tag is truthful and that no conflicting statements are made on the sack and tag.

TC-288—May 7, 1940

A group representing the feed industry called at the Administration to inquire specifically about the labeling of ingredients on sacks of feed. The spokesman stated that the prevailing practice in most of the States not only permitted but in most instances required that the ingredients and the guarantee legend appear on tags affixed to the sacks of feed. Such information may be duplicated in whole or in part on the main face of the sack, provided there is no discrepancy between the statements in the two places. Since the letter of the Federal Food, Drug, and Cosmetic Act requires all of the information necessary under the Act to be on the same label face or panel, the division of some of this information between the tag label and the sack would seem to violate at least technically that section of the Act. The visitors asked, in view of the complications involved in printing so many different sacks, whether it would be satisfactory to have the name and address of the manufacturer or distributor, the net weight statement, and brand name

on the face of the sack and the ingredients of the sack listed on the tag label.

"It was stated in reply that consideration must be given to the fact that the Federal Food, Drug, and Cosmetic Act was passed without specific reference to feeds. Inasmuch as Congress had not thought necessary to include specific regulations for feeds in this or any other Acts, consideration in our administrative procedure might be given to the requirements of the States under their specific feed control laws. Mr. \* \* \* assured Mr. Campbell that he spoke for the Association which represented the individual States and that they would not object to such a division of the labeling.

"Under the circumstances \* \* \* if the necessary information would be contributed to the buyer without requiring all of the list of ingredients to appear on the face of the sack, provided that what appears on the tag is truthful, and that no conflicting statements be made on tag and sack, no objection would be offered by this Administration."

**"LIQUID SUGAR"**

The term "Liquid Sugar" is inappropriate as a designation for partially inverted sugar sirup.

TC-289—May 7, 1940

"Several years ago there came to the attention of the Food and Drug Administration a product being used for manufacturing purposes consisting essentially of a solution of sugar and invert sugar in water under the name 'Liquid Sugar.' From time to time inquiries were made of the Food and Drug Administration as to this product. In reply to such inquiries the Food and Drug Administration advised that they did not

believe the term 'Liquid Sugar' was a suitable one for designating a partially inverted sugar sirup and that such name was likely to mislead consumers since the ordinary consumer of sugar and related products would not be advised by the name that such a product contained from 20 to 30 percent water and that in most instances the sugar present had not been refined to the same extent as ordinary granulated sugar."

**"ICE CREAM POWDER"**

The term "ice cream powder" should be restricted to a product which will make ice cream with the addition of water only.

TC-290—May 7, 1940

Comment was offered regarding the labeling of a product designated "\* \* \* Brand

Ice Cream Powder," which is composed of gum karaya, tapioca flour, and refined corn sugar.



"Obviously, from the composition of the article as you have described it, it is not a powder that will make ice cream simply by the addition of water, which the name 'ice cream powder' suggests. We advised manufacturers under the Food and Drugs Act of 1906, the requirements of which regarding the naming of a product of this kind were even more restricted than those under

the Act of 1938, that the name 'ice cream powder' is not appropriate for products consisting of ingredients sometimes used as a 'stabilizer' for ice cream. Also the statement 'for Ice Cream, Fruit Ices, Pie Fillings, etc.' accentuates the misleading impression given by the name 'ice cream powder.' \* \* \*

### CANNED PEAS—"TELEPHONE"

The unqualified expression "telephone" to indicate sieve size of canned peas constitutes misbranding.

TC-291—May 7, 1940

Correspondent inquires regarding the use of the expression "telephone" on canned pea labels.

"I am not aware that any recent official announcement of this Administration has taken the position that the word 'telephone' has, to the younger generation at least, any very strong varietal connotations when applied to peas. However, a casual inspection of a few 1940 seed catalogues shows that the term is still in use in a varietal sense by \* \* \*. In two of these the characteristic of eight to ten, or more peas per pod is mentioned. Be that as it may, it is a well-established doctrine of this Administration that so-called descriptive terms, which really are not descriptive at all and appear to convey no meaning whatever to the average unsophisticated consumer, must, by their very nature, inevitably confuse and, perhaps, mislead such a consumer. When we add to this that a very great many

people still carry memories of having planted 'telephone' peas in the days not too long past when this term did have an extremely important varietal significance, I believe that the sum total compels the observation that the unqualified expression 'telephone' on a canned pea label to indicate merely a No. 4 (or perhaps even larger) sieve size (and perhaps in the case of the sweet varieties only, rather than in both) would constitute a definite misbranding under the very strict terms of the Food, Drug, and Cosmetic Act.

"After all, there would seem to be no more accurate and satisfactory method of conveying to the consumer information on canned pea sizes than such clear-cut expressions as 'No. 2 sieve size,' 'No. 3 sieve size,' and so on, especially when such terms are supplemented, as is the case with some canners, with a facsimile of the size represented by the number used."

### "ITALIAN STYLE PEELED TOMATOES WITH ADDED PUREE"— LABELING

The letter discusses the manner of labeling product designated "Italian Style Peeled Tomatoes with Added Puree."

TC-292—May 7, 1940

Correspondent inquires about the labeling of Italian Style Peeled Tomatoes with Added Puree.

"As you are aware, no definition and standard for a commodity of this type has been promulgated. Definitions for tomato puree and for canned tomatoes have been established. If the article is canned peeled tomatoes corresponding with the definition for canned tomatoes already announced, and the packing medium is puree corresponding

with the definition for that article, if the fill of container corresponds to that specified for canned tomatoes, and if the article as a whole distinctly differs in appearance and characteristics from canned tomatoes, we believe a label 'Italian Style Peeled Tomatoes and Tomato Puree,' with the words 'tomato puree' given a degree of prominence essentially equal to that given to the word 'tomatoes', will meet the requirements of the statute."



**"GRENADINE"**

The name "Grenadine" is unobjectionable on a syrup containing a mixture of fruit juices having the characteristic grenadine flavor and color.

TC-293—May 7, 1940

"Originally, grenadine was prepared from pomegranate juice and sugar, but for many years the name has been loosely applied to syrups and beverages consisting of other fruit juices and sugar syrup. No objection has been made, therefore, to the use of the name 'Grenadine' on a syrup containing a mixture of fruit juices which has a characteristic grenadine flavor and color. The characteristic flavor can be obtained from a

mixture of black current juice and other fruit juices with the black current juice predominating. It may be that the characteristic grenadine flavor can be obtained also by other combinations of fruit juices, with or without a minute amount of spice or similar natural flavoring. The characteristic color of grenadine is red which is derived either from the fruit juices used or by the use of artificial color."

**OILS—OLEORESINS—OFFICIAL COMPENDIA**

If labels of oils, oleoresins, and other drugs refer to obsolete editions of official compendia, statement should also be made that articles are not recognized in current editions.

In the case of names at present recognized in the compendia, articles designated by such names, if they do not conform to the official specifications, must be labeled to show the nature and extent of each deviation. It is not sufficient merely to refer to some superseded edition of a compendium.

TC-294—May 7, 1940

"\* \* \* oils, oleoresins, and other drugs which were at one time recognized in either the *Pharmacopoeia* or the *National Formulary* but which are not recognized in the current edition of either of these texts, if labeled to show that they conform to some formerly official standard, should, we think, be prominently labeled also to show that the article is not recognized by the current edition of the official compendium mentioned. This would apply, for example, to Cajeput Oil, Cubeb Oil, Erigeron Oil, Pennyroyal Oil, and Black Pepper Oleoresin.

"In the case of the names at present recognized in the official compendia, Section 501 of the law requires that articles designated by such names, if they do not con-

form to the official specifications, shall be labeled to show the nature and extent of each deviation. In such instances it is not sufficient merely to refer to some superseded edition of the *Pharmacopoeia* or *National Formulary*, although there will be no objection to a statement, in addition to the required information with reference to deviation from the at present official specifications, that an article conforms to a specified text, preferably with the added statement that such text is no longer official. I assume that in every instance the identity of the article is not involved and that the respects in which the articles differ from the current requirements are in strength, quality, and purity only."

**OLIVE OIL—LABELING—FOREIGN LANGUAGE**

Letter discusses application of regulation under Section 403 (f) to panels of can of olive oil and to circular containing representations in foreign language.

TC-295—May 7, 1940

Correspondent requests an interpretation of the foreign language labeling requirements under regulations (c)(1), (2) and (3) under Section 403(f) in the case of certain types of packages, particularly olive oil cans, one main panel of which is all in English and the other main panel of which is all in Italian.

"We are disposed to regard the requirements as having been met with respect to the mandatory label information if one display panel is entirely in English and bears the mandatory label information, and the opposite display panel is entirely in the foreign language and bears all of the mandatory label information.

"You also raise the question as to wheth-



er, in case a circular making representations in a foreign language accompanies the article, the label must bear the mandatory information in the language used in the circular. Regulation 403(f), paragraph (c)(3) means that the mandatory information, whether required on the label or on the

labeling, must appear on the foreign language circular. The use of such a circular does not necessitate the use of the foreign language on the label. If, however, the foreign language is used on the label to give mandatory information, such information does not have to be repeated in the circular."

### NUTS—LABELING

Letter discusses the labeling of assorted nuts when the ingredients vary.

Administration is not insisting that the name of the specific oil in which salted nuts are cooked be declared in the ingredient list. Cellophane bag in which nut is packed should bear reference to specific kind of nut contained.

TC-296—May 7, 1940

"In the event the assortment of nuts \* \* \* varies from time to time, Regulation 403 (I)(e)(2) \* \* \* provides for an exemption from compliance with Section 403(i)(2) of the Act regarding any ingredient which is not common to all packages. For example, if your assortment of nuts always included cashews, almonds, and Brazil nuts but not always pecans and peanuts, the label might state 'Contains cashews, almonds, and Brazil nuts—May also contain pecans and peanuts.'"

Correspondent's letter deals with the labeling of small cellophane bags containing salted nuts.

"In view of the fact that the vegetable oil ingredient is present in residual traces only

as a result of the previous cooking of the nuts in the oil, we have not insisted that the name of the specific oil used be stated on the label. However, we do feel that in general, the public has a definite interest in knowing the kind of nut being purchased. In order to insure compliance, we suggest that the specific name of the particular nut be prominently declared on the label. In order that the same cellophane bags can be used for different kinds of nuts at different times, there would be no objection to inserting a slip with the name of the particular nut underneath the cellophane, or clipping a paper slip to the bag, giving the name of the particular nut, provided it is conspicuous."

### CHOCOLATE FLAVORED MALTED MILK

A product should not be named "Chocolate flavored sweetened malted milk" unless it contains a sufficient proportion of malted milk so that when used according to directions it will produce a beverage of the composition ordinarily dispensed at soda fountains as chocolate flavored malted milk

TC-297—May 7, 1940

"\* \* \* we can state that the product should not be named 'Chocolate flavored sweetened malted milk' unless it contains a sufficient proportion of malted milk so that when used according to directions it will produce a beverage of the composition ordinarily dispensed at soda fountains as chocolate flavored malted milk. \* \* \*

"From the manufacturing formula \* \* \* we estimate that after the volume of your product has been expanded by agitation in the dispensing operation, the finished bev-

erage will contain slightly less than 0.3 ounce of malted milk in each 10 fluid ounces. An investigation which we made some years ago showed that malted milk drinks as served at soda fountains normally contain at least 0.5 ounce of malted milk in 10 fluid ounces of beverage. We believe that if you retain the name 'Chocolate Flavored Malted Milk Drink' for your product, the manufacturing formula should be revised so that the finished beverage will contain at least 0.5 ounce of malted milk in 10 fluid ounces of beverage. \* \* \*



## HONEY

The term "Extracted Honey" or "Strained Honey" implies honey in the liquid form, not partially granulated.

TC-298—May 7, 1940

"If purchasers expect honey that is labeled 'Extracted Honey' or 'Strained Honey' to be liquid honey, as we believe is the case, it would constitute misbranding to ship in interstate commerce a partially granulated honey labeled in this way. However, as you know, the granulation or the crystallization of dextrose may occur in honey on the shelves of the dealer after the packer ships it. Of course when honey is marketed in

bottles, it is possible for the purchaser to note the change in the appearance of the honey by inspection before purchase.

"It is not clear to us at this time how the situation you describe can be corrected by labeling since the granulation or crystallization of dextrose may or may not occur in unprocessed extracted honey, and as you indicate in your letter, may even occur in processed honey after a period of time.  
\* \* \*

SOUPS—EVAPORATED MILK—QUANTITY OF CONTENTS  
DECLARATION

The quantity of contents declaration of ready-to-serve liquid soups and evaporated milk should be in terms of fluid measure.

The Administration is not insisting that q.c. of so-called "condensed" or semi-solid groups be in terms of fluid measure.

TC-299—May 7, 1940

Correspondent requests information as to the proper manner to declare the contents of various liquid foods. In reply, he was referred to the Regulation in paragraph (c)(2) under Section 403(e)(2), and comment was made as follows:

"You will note that no preference is given to trade practice under the new regulation; that general consumer usage is to prevail where such usage exists and, if not, liquid foods shall be declared in terms of liquid measure. We believe consumers, in general, think of canned evaporated milk and liquid soups in terms of liquid measure and that, therefore, the regulation requires these commodities to be declared in terms of liquid measure. Even if no general consumer usage existed, the regulation would still call for a declaration of the quantity of

contents of these articles in terms of fluid measure.

"Some uncertainty has been expressed to us in regard to the status of canned soups of a viscous or semisolid consistency which are intended to be diluted with an equal volume of water before use, such as some so-called condensed soups. We have not reached a definite conclusion in our own mind yet as to whether consumers in general think of such soups in terms of weight or of measure, and, therefore, we are not insisting at this time that in the case of such soups the declaration be in terms of fluid measure. In the case of any of the articles discussed, evaporated milk, canned liquid soups, and canned semisolid soups, there is, of course, no objection to declaring the quantity of contents in terms of both weight and fluid measure."

CANNED FRUITS AND VEGETABLES—"SUPREME QUALITY"—  
"FANCY"

The term "Supreme Quality" is unobjectionable on labels of food products (particularly canned fruits and vegetables) of the highest recognized grade.

Trade practice is responsible for the significance of grade designation "Fancy." The term is not used in identity standards.

TC-300—May 7, 1940

Correspondent inquires as to the appropriateness of the term "Supreme Quality" when used as a part of the brand designa-

tion on labels for canned fruits and vegetables.

"The suitability of this term must be considered in the light of the requirements of



Section 403(a), which classes a food as misbranded if its labeling is false or misleading in any particular. It is sometimes difficult in the absence of a survey of consumer opinion to decide whether or not the given expression or word is liable to mislead. Unless it develops that the use of the term in question does actually mislead consumers, we would not be disposed to object to its use on the label of a product which is of

the highest recognized grade of the particular article.

"The significance of the grade designation 'Fancy' and of the other grade designations mentioned in your letter has largely been established through trade practice, and these terms are not used in definitions and standards of identity for canned fruits and vegetables promulgated under the Food, Drug, and Cosmetic Act."

### DRUGS—BROMIDES—ACETANILID

Letter sets forth the position of the Administration with respect to the quantities of bromides and acetanilid, singly or in combination, which would cause medicines containing them to be considered dangerous under Section 502 (j).

TC-301—July 2, 1940

"During the course of a telephone conversation several days ago, you asked for a concise statement concerning the position of this Administration with respect to the quantities of bromides and acetanilid which either singly or in combination would, in our judgment, cause medicines containing them to be considered as dangerous drugs within the meaning of Section 502(j) of the Act.

"A comprehensive investigation which has been conducted by this Administration has led to the conclusion that these ingredients will cause medicines to violate Section 502 (j) of the Act in the following circumstances:

"(1) **Bromides:** Those medicines that provide, when consumed according to the directions for use, a total daily dosage of more than 30 grains of sodium bromide, or more than 15 grains of that salt during any three-hour period.

"(2) **Acetanilid:** Those medicines that provide, when consumed according to the di-

rections for use, a total daily dosage of more than 5 grains, or more than  $2\frac{1}{2}$  grains during any three-hour period.

"(3) **Combinations of bromides and acetanilid:** Those medicines that provide, when consumed according to the directions for use, a total daily dosage of more than 15 grains of sodium bromide and 5 grains of acetanilid, or more than  $7\frac{1}{2}$  grains of sodium bromide and  $2\frac{1}{2}$  grains of acetanilid during any three-hour period.

"These comments apply also, of course, to the medicinal bromides other than sodium bromide.

"These views are based on present-day scientific information, but the opinions expressed may be modified as the development of new information and facts may warrant.

"Preparations containing the amounts of bromides and/or acetanilid mentioned, or smaller amounts, may be subject to action if they fail to bear in their labelings adequate directions for use or adequate warnings."

### "AMPULING" AND SUBSEQUENT STERILIZATION— MANUFACTURING

The "ampuling" and subsequent sterilization of posterior pituitary extract constitute a manufacturing process.

TC-302—August 20, 1940

"We would regard the ampuling and subsequent sterilization of posterior pituitary extract as constituting a manufacturing pro-

cess. We will therefore not take exception to the appearance of your name and address without qualification on the labels of products so prepared."



**"NO NARCOTICS OR OPIATES"—CATHARTICS**

The general use of the phrase "No Narcotics or Opiates" has been discouraged. It is considered unwarranted on the label of an active cathartic.

TC-303—August 20, 1940

"\* \* \* With reference to the statement 'No Narcotics or Opiates', there may be types of products where such a statement is informative and justifiable. We think, however, that there is a definite possibility that this statement will be interpreted by

lay users as tantamount to an assertion that the article contains no potentially harmful ingredients. We have been disposed to discourage the general use of this phrase \* \* \* and believe it to be unwarranted on an active cathartic such as the one under consideration \* \* \*."

**COMMON CARRIERS**

A common carrier which labels and distributes merchandise incurs the same responsibility as any other interstate shipper or receiver.

TC-304—August 20, 1940

A transportation company asked for information concerning the responsibility of a common carrier in connection with the relabeling of merchandise which, for one reason or another, had come into its possession for disposition.

"The proviso in Section 703 grants immunity from prosecution to carriers by reason of their receipt, carriage, holding, or delivery of products subject to the Act in the usual course of business as carriers. The immunity does not extend to relabeling and this would, accordingly, be considered a function outside the duties of a carrier.

Irrespective of whether or not a carrier has any title or interest in the goods, such carrier would be subject to the same responsibility as any one else applying a label to goods shipped in interstate commerce and in violation of the law. It is not believed that a carrier in relabeling goods can claim exemption as an agent or employee of the original shipper, nor is it likely that the carrier can protect itself by a guaranty, as mentioned in Section 303(c). Our answer to the inquiry is that a carrier acting otherwise than as specified in Section 703 incurs the same responsibility as any one else shipping or receiving goods in interstate commerce in violation of the law."

**CANNED TOMATOES WITH TOMATO PASTE**

Tomato paste is not a recognized packing medium in the identity standard for canned tomatoes. No form of labeling would legalize a food differing from the standard but simulating the standardized food.

TC-305—August 20, 1940

In response to inquiries relative to the labeling of canned tomatoes packed with the addition of tomato paste, correspondent was advised as follows:

"In our letter \* \* \* to you we pointed out that if the addition of tomato paste renders the article sufficiently different in general characteristics from canned tomatoes, it might be regarded as a different article from ordinary canned tomatoes and labeled as a mixture of tomatoes and tomato paste.

"In your reply \* \* \* you indicate that \* \* \* in your opinion the addition of tomato paste in the process of packing toma-

atoes does not render the article sufficiently different in general characteristics that it may be regarded as a different article from canned tomatoes. You point out that the article in its ultimate appearance is nothing else than canned tomatoes with very heavy puree.

"We call your attention to Section 403(g) \* \* \* of the Act. The opinion in our letter \* \* \* was, of course, predicated upon there being a sufficient difference in the general characteristics of canned tomatoes and canned tomatoes with added tomato paste so that the latter article does not purport to be canned tomatoes. It is entirely a question of fact. If the product actually is so



close in appearance and general characteristics to standardized canned tomatoes that it in effect purports to be that article or is represented to be that article, then all we can do is to point to the omission of a provision in the Food, Drug, and Cosmetic Act defining the legal status of a product which purports to be or is represented as a food for which a standard of identity has been promulgated but which fails to comply with that standard. Tomato paste is not a recognized packing medium in the identity standard for canned tomatoes.

"Until the courts have had an opportunity to interpret this section of the Act, it seems to us the only safe assumption to make is

that no form of labeling would legalize a food differing from the definition and standard of identity but whose general characteristics of appearance, taste, manner of packing and sale closely simulate those of the standardized food. If, as you apparently feel, canned tomatoes with added tomato paste do have essentially the same characteristics as canned tomatoes, then the only way we know of to seek recognition of tomato paste as a recognized ingredient in canned tomatoes is by means of a public hearing on a proposal to amend the standard for canned tomatoes, as provided for in Section 701(e) on page 36 of the Act. \* \* \*

### SIMPLE ANALGESIC—MINOR PAINS—MENSTRUATION

A simple analgesic may be labeled with claims for temporarily relieving minor pains, but should not bear labeling implying that it is a specific for pains associated with menstruation.

TC-306—August 20, 1940

"It is our understanding that these tablets consist of five grains aspirin, five grains caffeine citrated and five grains capsicum. There would, of course, be no objection to describing this article as capable of temporarily relieving minor pains. It is the view of our medical staff that the therapeutic activity of the medicine does not justify

the claim that it will relieve depression associated with menstrual periods. The article is, of course, in no sense a specific for menstrual pains. The label should, in our opinion, make it clear that the product tends to temporarily relieve minor pains and should not imply that it is a specific for those associated with menstruation. \* \* \*

### SALAD DRESSING—SPECIFIC STARCHES

The Administration is presently disposed to regard it as unnecessary to name the specific starches in the case of salad dressing.

TC-307—August 20, 1940

"We have your letter of \* \* \* asking whether it is necessary to name the specific starches in the case of salad dressing.

"The Administration is at this time disposed to regard it unnecessary to name the

specific starch, but if failure to do so results in deception or in withholding information from the public to which it is entitled it would, of course, be necessary to rescind this and advise manufacturers to declare the specific starch used."

### "SPICE FLAVORINGS"

The designation "spice flavorings" is misleading if applied to essential oils of spices used in food. The letter discusses the manner of designating extractives from spices used in food.

TC-308—August 20, 1940

In response to an inquiry as to the appropriateness of the designation "spice flavorings" in a label ingredient list for a food product, when essential oils of spices instead of the spices themselves are used, the following reply was made.

"As you know, the Food, Drug, and Cosmetic Act permits the designation of spices and flavorings as spices and flavorings without naming each as an ingredient if present in foods fabricated from two or more ingredients. Under this provision we have raised no objection to the designation



of spice oils as flavors. They are not 'spices' and therefore are not appropriately designated as 'spices' on the label. The name 'spice flavorings' permits the ready inference that the flavoring present is a result of spices added in the form very extensively employed to get spice flavor effect in food that is, as whole or ground spices and not as essential oils of spices. Under the circumstances, the name 'spice flavoring' would in our opinion be misleading and would accordingly constitute misbranding. The term 'spice oil flavoring' would probably not be subject to the same criticism.

"If it is desired to designate more specifically the nature of the flavoring, this ingredient can be named after the name of the spice from which it is derived, as for example, 'oil of cloves' or 'flavored with oil

of cloves.'

"We are glad to be corrected as to the identity of the substances which you had in mind. We had assumed erroneously that you were concerned with the essential oils of spices. It now appears that the flavoring ingredient is extracted from the spice by a solvent, the solvent evaporated, and the extractives fixed in a base such as salt or dextrose to facilitate even mixture in the food to which they are added.

"In the light of these facts, we are not disposed to object to the designation 'Flavored with Spice Extractives' or 'Spice Extractive Flavoring' or, of course, just 'Flavoring.' There would be no objection in the case of specific spice extractives to the phrase you suggest 'Flavored (or Seasoned) with Clove Extractives.'"

### "TOMATO HOT SAUCE"—LABELING

The letter discusses the manner of labeling "tomato hot sauce."

TC-309—August 20, 1940

"We have recently had a request \* \* \* to furnish you with an opinion on the labeling of 'tomato hot sauce', which we assume is the usual product prepared from tomato puree, peppers, and possibly spices and other seasonings.

"It is our understanding that the point with which you are concerned is the name to be applied, in the listing of ingredients, to a tomato puree (or pulp) prepared by straining peelings, trimmings and cores (the residue from preparing tomatoes for canning.)

"No standards have been established for the product known as 'tomato hot sauce', and it is therefore necessary to declare the presence of all its ingredients in the labeling, as specified in Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act.

"In accordance with the provisions of regulation (a) under Section 403(i)(2), to-

mato puree may be declared on the label of the food to which it is added by the name specified in the definition and standard of identity for tomato puree, which appears under Section 53.020 on page 3326 of the Federal Register for July 18-1939. If the tomato puree used has been prepared from optional ingredients (2) and/or (3) listed in the standard, it is necessary that the product name of the ingredient 'tomato puree' be supplemented by a statement showing its optional ingredients. Subsection (3)(b) of the tomato puree standard specifies the terms that must be used to indicate the optional ingredients from which the puree has been prepared. For instance, the name of 'tomato puree' prepared from the liquid obtained from the residue from preparing tomatoes for canning (peelings, trimmings, and cores) must be qualified with the term 'Made From Residual Tomato Material From Canning.'"

### WARNINGS IN LABELING OF DRUG PRODUCTS

The letter discusses the placement of warnings in drug products. Generally speaking, the spirit of the law can best be observed by placing both the warnings and the directions upon a label attached to the immediate container and also upon the outside of the package.

TC-310—August 20, 1940

"We find it difficult to reply responsively to your inquiry \* \* \* regarding the position which should be occupied by the warn-

ings on drug products, since the circumstances involved in any particular case must be taken into consideration. We may say, however, that while Section 502(f) speci-



fies that the warnings shall be in the labeling, which term is defined by Section 201 (m) as including 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles,' Section 502(c) requires that the mandatory information appear 'prominently,' 'with such conspicuousness \* \* \* as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'

"It was obviously the intent of Congress that the warnings should be given in such fashion as certainly to reach the notice and arrest the attention of the purchaser. We are of the opinion that the directions for use and the warnings should be brought together so that the consumer will have before him in one place full information as to

when and how to take and not to take the medicine. We do not think that the placing of directions for use on the outside container and omitting the warnings would constitute appropriate labeling even though the directions were repeated with the warnings on a stuffer within the container. Generally speaking, we think that the spirit of the law can best be observed by placing both the warnings and the directions for use upon a label attached to the immediate container of the medicine and also upon the outside of the package where they will be available to the prospective purchaser before the purchase is consummated. It would not, of course, be necessary that this information be placed upon the front of the carton or upon the principal bottle label. They might very well occupy the back panels where there is room."

### DULCIN—SACCHARIN

The letter discusses the use of saccharin and dulcin in food and the necessary labeling of food products containing them.

TC-311 (corrected copy)—  
August 20, 1940

In response to an inquiry regarding the use of saccharin for sweetening food, the following reply was made:

"Saccharin has no food value and its use in food is held to constitute adulteration under Section 402 (b) of the Food, Drug, and Cosmetic Act unless the article is clearly labeled to show that it contains saccharin, a nonnutritive artificial sweetener, and that it is to be used only by those who must restrict their intake of ordinary sweets.

"If so labeled the article will be considered as falling within the scope of Section 403(j) of the Act, which deals with food for special dietary uses, including food con-

taining, saccharin. Notices regarding the regulations referred to in this section will be published in the Federal Register."

Regarding the use of dulcin (paraphenetol carbamide) in food:

"Dulcin, like saccharin, has no food value and its use in food is held to constitute an adulteration under Section 402(b) of the Act, unless the article is clearly labeled to show that it contains dulcin, a nonnutritive artificial sweetener, and that it is to be used only by those who must restrict their intake of ordinary sweets.

"If so labeled the article will be considered as falling within the scope of Section 403(j) of the Act, which deals with food for special dietary uses, \* \* \*."

### LIGHT MINERAL OIL

If light white mineral oil is sold as a laxative, its label should clearly state that the product is not heavy oil and that the dose is materially less. The directions for use should advise a further reduction if leakage occurs.

TC-312—August 20, 1940

"Replying to your letter \* \* \* regarding the sale of light white mineral oil for internal use, the Administration will not adversely criticize such label recommendation. The effective dose, however, is materially less than that for the heavy oil. If given in the dosage required for the heavy oil, leakage is apt to occur. If you decide to market the light oil for use as a laxative,

we suggest that the label make it perfectly clear that the product is not the heavy oil and that the dose is materially less. We suggest also that the directions for use advise a further reduction of the dose if leakage does occur. Of course the same warning with respect to the time at which the article is to be taken applies to both varieties of liquid petrolatum."



**DIGITALIS—POTENCY—CAT UNITS**

If the potency of digitalis is expressed in terms of cat units, the method by which such potency is determined should be specified.

TC-313—August 20, 1940

"Replying to your inquiry \* \* \* regarding the labeling of digitalis in terms of cat units, the Administration is of the opinion that since the literature contains various procedures for determining the potency of digitalis by measuring its effects upon a cat, any product which is labeled in terms of cat units should specify, in connection with the declaration, the method by which such potency is determined. This, we think, is a material fact required under Section 201 (n) of the Federal Food, Drug, and Cosmetic Act. Incidentally it should be noted that there may be several variations in the

details of the Hatcher-Brody procedure. We, therefore, think that the manufacturer or distributor of a digitalis preparation, the labeling of which refers to the Hatcher-Brody method, should be rather specific in indicating the exact details used in the standardization.

"The Administration has not undertaken to announce any tolerances in connection with the determination of digitalis potency by any of the various methods employing the cat as the test animal. The declared potency when thus expressed should be accurate within the limits of accuracy of the method in the hands of a skilled technician."

**AMPULS—LABELING**

To the extent practicable, the labels of individual ampuls should carry the information required by the Act.

TC-314—August 20, 1940

Correspondent asked for our opinion as to the requirements of the law with reference to the labeling of ampuls.

"We have given this matter careful consideration and are of the opinion that, to the extent that it is practicable, the labels of individual ampuls should carry the information required by the law. Where the size of the ampul does not permit the placing upon the ampuls of all the information required under ordinary circumstances to appear upon the label, we think the

label should carry as much as practicable of such information to the exclusion of information not required. \* \* \*

"As you know, the regulations provide that when, because of limited space, any of the required information is to be omitted the statement of the quantity of contents may be omitted (Regulation (m)(1) under Section 502(b)); and a concession as to conspicuousness is made with reference to the listing of active ingredients, (Regulation (f)(1) under Section 502(e))."

**VITAMIN-CARRYING OIL—LABELING**

The letter discusses the labeling of a vitamin-carrying oil intended for human consumption.

TC-315—August 20, 1940

Correspondent was advised as follows regarding the proposed labeling for a vitamin carrying oil intended for human consumption.

"It is our understanding that the product you intend to market will consist of a concentrate of fish liver oils which supply vitamins A and D and \* \* \* oil, blended with pure edible cottonseed oil. The label of the product will carry an accurate statement of the vitamin A and D content of the mixture. You expressed the view that the primary purpose of such an article is to supply vitamins A and D. \* \* \* In our discussion of this with you, reference was

made to certain sections of the Act which require that information concerning the ingredients of both foods and drugs shall appear conspicuously on the label. Since a product of this nature is likely to fall within the scope of Section 403(j) of the Act, any comments we have offered must be considered as subject to further clarification after final regulations under Section 403(j) have been promulgated. Our position that the product may fall within the scope of this section does not imply the product may not also be considered a drug, since the definitions for foods and drugs are not mutually exclusive.



"A fully informative statement of the ingredients of this product would state that the article is a vitamin-containing oil for human consumption, consisting of natural vitamins A and D from a concentrate of cod liver oil, (or whatever the source of the concentrate might be), \* \* \* oil, blended with pure edible cottonseed oil. You indicate, however, that it may be necessary for you to change the formula and substitute for the \* \* \* oil some other fish oil, such as salmon. Similar substitution of peanut oil or some other edible vegetable oil for the cottonseed oil may be made. These changes would be necessitated by the variability in supply of the particular oils. You point out that such changes in ingredients would present labeling difficulties if the specific name of the oils were required.

"In lieu of the manner of stating the ingredients mentioned above, you suggest that the requirement for listing ingredients be met by a statement such as 'Consists of natural vitamins A and D from a concen-

trate of fish liver oil blended with the fish oils and a pure edible vegetable oil.' Some time ago, the Secretary considered a petition by the manufacturers of salad oils for exemption from the labeling requirements of Section 403(i)(2), based on considerations similar to those presented by you. The petition was denied, but exception was not taken to the declaration of the oil ingredient as 'vegetable oil.' In view of this, we will not for the present take exception to the listing of the ingredients in the manner which you propose. We do reserve the right, however, to change our position in this matter if it should develop that the consumer is being deprived of information to which he is entitled under the provisions of the Act. This position is also predicated upon the understanding that no reference is made to a specific oil if such oil is not in fact present in the mixture and the product is represented only as a source of vitamins A and D. \* \* \*

### CLINICAL THERMOMETERS

Clinical thermometers are classified as devices subject to the Act.

TC-316—August 20, 1940

"In response to several inquiries we have discussed the application of the Food, Drug, and Cosmetic Act to clinical thermometers.

"It is the view of the Food and Drug Administration that clinical thermometers are devices within the meaning of Section 201 (h) of the Food, Drug, and Cosmetic Act.

"Examination of clinical thermometers shows that some instruments fail to give a reliable reading under normal conditions of use or when used as directed on the labeling. Such instruments thus fail to meet the requirements of Section 501(c).

"Some instruments fail to bear on their labeling adequate directions for use relating to the length of time required by the instrument to give an accurate reading under ordinary conditions of use. Such instruments, if sold in interstate commerce, do not comply with the provisions of Section 502 (f)(1) of the Act. It is our opinion that to meet the requirements of

Section 502(f)(1) and 502 (c) it will be necessary that such adequate directions be placed upon the thermometer itself. If the instrument is sold with a case in which the thermometer is carried during its period of use, the purpose of the Act may possibly be fulfilled by imprinting such directions upon this case in lieu of the instrument itself. Likewise, such a representation as '1 minute thermometer' or '3 minute thermometer' is false and misleading and thus comes within prohibition of Section 502 (a), unless it refers accurately to the time it will take the instrument to give a reliable reading under ordinary conditions of use. Representations relating to certification are also misleading unless the instrument itself has been reliably tested and certified.

"\* \* \* It is our interpretation of the purpose of the Act that a statement concerning the name and address of the manufacturer and a statement relative to the minimum time of insertion is all that need be carried on the instrument or its case.\* \* \*



### SODIUM BISULPHITE—CONFECTIONERY

Further consideration has been given to the addition of sodium bisulphite to candy. It is regarded as a nonnutritive substance whose use in confectionery is prohibited by Section 402(d).

TC-317 (Revokes TC-241)—  
August 20, 1940

"\* \* \* we wrote you in reply to your telephone inquiry as to whether sodium bisulphite when added to candy may under the Food, Drug, and Cosmetic Act be declared on the label merely as a preservative or as sodium bisulphite. In our reply we suggested that a proper form of declaration would be 'Preserved with Sodium Bisulphite' or 'Contains Sodium Bisulphite, A Chemical Preservative.' Since that time fur-

ther consideration has been given to the status of sodium bisulphite in confectionery and the conclusion reached that this chemical is a nonnutritive substance and, therefore, under the provision of Section 402(d) of the Food, Drug, and Cosmetic Act may not be used in confectionery in any amount.

"The purpose of this letter is to acquaint you with this opinion and cancel our letter to you of \* \* \*."

### GELATIN DESSERT PACKAGES—FILL

To avoid deception, a package of gelatin dessert should be one having a maximum percentage of fill and a minimum amount of unfavorable space occupied by other than the food.

TC-318—August 20, 1940

Correspondent's letter refers to "approval" of a certain type of gelatin dessert package, as remodeled.

"Presumably you have in mind a recent visit to the Administration with several gelatin dessert manufacturers, at which time packages and packaging problems were discussed from the standpoint of the deceptive package provision of the Food, Drug, and Cosmetic Act. We are at a loss, however, to understand what basis you have for concluding that any proposed type of package was approved at that meeting. We, of course, have no authority to approve any package, and I pointed out distinctly that the proposed gelatin dessert package of the satchel type under discussion was not approved, that we could not undertake to say

whether or not it would prove misleading inasmuch as the courts would have to decide that, and that those manufacturers who chose to adopt it would do so on their own responsibility.

"I undertook to say to the manufacturers at that meeting that this Administration would not undertake to manage the industry's own business by dictating the specific size and type of package it should use. I said that the industry itself was in a position to standardize its packages in conformity with the deceptive package provision of the law and that such a standardized package would be one which would have the maximum percentage of fill and the minimum amount of unavoidable space occupied by other than the food and that this was the goal which the industry should strive for."

### OINTMENT CONTAINING MERCURIAL LIPOID—LABELING

In view of the doubt in connection with the exact chemical composition of a mercury lipid, the label of an ointment containing it should indicate the proportion of the mercury lipid present and its equivalent in metallic mercury.

TC-319—August 20, 1940

"You have inquired how the mercury content of an ointment containing a mercurial lipid should be declared. Section 502 (e) provides for the quantitative declaration of mercury or any derivative or preparation of this substance. The ointment mentioned by you does not contain mercury but does contain a mercury derivative. If the article has no common name, it should be declared

quantitatively under the chemical name. In view of the doubt in connection with the exact chemical composition of a mercury lipid, we believe that the label should indicate the proportion of the mercury lipid present in the article and in addition its equivalent in metallic mercury. The amount of mercury in the product and not that in the mercury lipid should be declared."



## MIXTURE OF DISTILLED AND CIDER VINEGAR

The letter discusses the labeling of a mixture of distilled and cider vinegar.

TC-320—August 20, 1940

"As we understand the process, you apparently distil alcohol from cider vinegar stock and to the distillate add cider vinegar stock and then convert the alcohol in the mixture into acetic acid of a finished vinegar by the usual generator process, coming out with a vinegar running around ten per cent acetic acid strength or 100 grain. As you know from the standards which have been in effect for a number of years, distilled vinegar is the vinegar obtained by the acetous fermentation of diluted distilled alcohol. No restriction is made in the standard as to the source of the alcohol. Obviously, where the vinegar is made from distilled alcohol without addition of other cider vinegar stock before generation the product is a distilled vinegar, and the vine-

gar made from the pure apple cider stock without admixture of alcohol obtained by distillation is a cider vinegar. The mixture of both raw materials, the alcohol and the cider stock, before generation would have no effect on the identity of the finished product. It is essentially a mixture of distilled and cider vinegars the same as though the vinegars had been independently produced and then mixed.

"The name '100 grain distilled cider vinegar' is obviously not appropriate for this product. We believe it should be designated as a 'blend of cider and distilled vinegar.' In connection with the name 'distilled vinegar' the label might bear additional information showing that the distilled vinegar was obtained from apple cider stock."

## CANNED PEAS—SIZES

The letter discusses the label designation of the size of canned peas.

TC-321—September 5, 1940

"\* \* \* your letter \* \* \* is one of several recently received on the question of the more or less vague term in use on canned pea labels instead of a clear statement of pea size in terms readily understandable to the average unsophisticated consumer.

"Your immediate question is of course more easily disposed of than the larger one of which it forms only one aspect. There has been no change in our position, announced in 1923, that the size designation 'Petit Pois' is inapplicable to peas larger than the No. 1 sieve size, that is to peas which in the raw condition will not pass a 9/32" mesh screen. As under the old Act, we are prepared to take action against this form of misbranding.

"Indeed, under the present very specific regulations as to the labeling of canned peas there is every reason to re-examine the whole chaotic situation of nebulous and even misleading terms for pea sizes, if the consumer is to obtain the useful information the regulation calls for, unobscured by incidental information such as pea size, which, as is well known, has today no direct correlation with eating quality except, perhaps, within a given pack of peas.

"It is accordingly our view that the only label designation of pea size entirely without objection is a facsimile of the size actually

present in the can. However, we will not raise objection for the present to statements in terms of sieve size, such as 'No. 2 sieve size,' etc., since there is reasonable agreement and fairly widespread understanding as to the meaning of these terms. Where the canner elects to use size terms which are such on their face e.g. 'Petit Pois,' 'Small,' 'Medium Small,' and the like, we believe that they should be accompanied by a statement of sieve size (or of average pea diameter in thirty-seconds of an inch). Other terms which have no clear size connotation to the consumer, and which may even give an entirely false impression as to variety or quality or both, are regarded as misbrandings in the light of Sections 403(a) and 201(n) of the Food, Drug, and Cosmetic Act. We have already advised correspondents that 'Telephone' is in this category, and the same would be true of such terms as 'Midgets,' 'Sifted,' 'Melting,' 'Gems,' etc."

"\* \* \* In our opinion if the extreme sizes of peas are removed from the run by grading, the remainder could not properly be labeled as 'Ungraded.' For the present, and without prejudice to the possibility of a change in viewpoint should the expression be misinterpreted, we would offer no objection to the statement 'Nos. 3, 4, and 5 Sieve Sizes' or to the expression 'Mixed Sizes.'"



**SALAD OILS—ANTI-OXIDENTS—MAYONNAISE**

Specific regulations have not been issued on the use of anti-oxidents in salad oils. It is the responsibility of a manufacturer to establish the harmlessness of the ingredient before using it. Where a chemical preservative is added, the labeling must reveal the common or usual name of the preservative and contain a statement of the addition of the preservative. If the name of the preservative is recognized by the consumer as that of a chemical preservative, it would only be necessary to declare the preservative by name.

Mayonnaise has been temporarily exempted from the requirement for a label declaration of ingredients. It is not exempted, however, from the requirement of the declaration of added substances not normal to it or from the declaration of the fact that preservatives have been added.

TC-322—September 5, 1940

"The Food and Drug Administration has issued no specific regulations on the use of anti-oxidants in salad oils. Proposals have been made from time to time for the addition of various substances, some of which are definitely toxic. It is the responsibility of each manufacturer who proposes to add foreign materials to foods to establish the harmlessness of the substances before doing so. No general list of approved substances has been issued. Where chemical preservatives of unquestioned harmlessness are added to oils, the labeling of the container—whether it be a 400-pound drum or a 5-gallon can—would be required to bear an adequate and conspicuous statement of the presence of the substances by their common or usual names. We have had no disposition to insist upon the labeling of shipments in tank cars. Distributors of such bulk shipments will presumably prefer to take advantage of the exemption established under Section 405 of the Food, Drug, and Cosmetic Act.

"In view of the fact that the action of the added substances is stated to be one of preservation, the provision of Section 403 (k) of the Act is pertinent. It requires food containing a chemical preservative to bear 'labeling stating that fact.' You will note from Regulation (a)(3) under Section 403 (k) that sugar is not classed as a chemical preservative. In the employment of the soy bean oil in the manufacture of other food

products it would be necessary that the label of such food products also bear the statement of the addition of the preservative.

"The language of Section 403(k) does not specifically say that the name of the preservative be given. However, since the preservative is also an 'ingredient,' Section 403 (i)(2) does require it to be specifically named. If the name itself is immediately recognized by the consumer as that of a chemical preservative, it would only be necessary to declare the preservative by name. However, if the public does not generally recognize the name of some substance as that of a chemical preservative, then the label statement should include the common or usual name of the substance followed by some such phrase as 'a chemical preservative.' If a fabricated food product contains two or more chemical preservatives contributed by different ingredients, they can be indicated by their specific names and the explanatory words 'chemical preservatives.'

"Mayonnaise has been temporarily exempted from the requirement for a label declaration of the ingredients which go to make up the product. This, however, does not exempt mayonnaise from the requirements of the declaration of added substances not normal to mayonnaise or from the declaration of the fact that preservatives are added when they are present."

**AGAR-AGAR—PSYLLIUM SEED—LAXATIVE WARNINGS**

Laxative warnings need not appear in labeling of agar-agar or products containing only gelatinous material from psyllium seed.

TC-323—September 5, 1940

"There have been no changes in the views expressed by the Administration with respect to warnings which should appear in the labeling of laxatives. We have not,

however, suggested that warnings need appear in the labeling of products like agar-agar and others that contain only the gelatinous material from psyllium seed. \* \* \*



**DRUG PRODUCTS—LISTING OF INGREDIENTS— SECTION 201(n)**

If the ingredients of a drug product are listed in a manner suggesting that all are mentioned, the list should be complete. A distinction should be made between active substances and inert ingredients.

Active ingredients should be listed in the order of their importance. Consideration should be given to the question of whether, under Section 201(n), some explanation is in order as to the comparatively negligible effect of some of the listed ingredients.

TC-324—September 5, 1940

"The Food, Drug, and Cosmetic Act, as you know, does not require a complete formula disclosure nor even a complete listing of all ingredients in a drug product. It does, however, specifically call for a revelation of the common or usual name of each active ingredient. While, of course, there is no legal objection to disclosure of all the ingredients, we think there is no doubt that if the label purports to give the entire list, \* \* \* all constituents including sugar and water should be named. Manifestly such a complete list does not in itself meet the requirement that the active ingredients be named unless they are definitely set apart and designated as active and clearly and unmistakably distinguished from inert constituents and solvents. The incomplete list on the \* \* \* label not only fails to segregate and designate the active ingredients but is intermingled with such non-required

statements as 'pleasant tasting,' 'scientifically blended,' \* \* \*.

"The adult dose recommended is one tablespoonful. This contains an average dose of fluidextract of senna, somewhat less than one-half an average dose of aromatic cascara sagrada fluidextract, and considerably smaller proportions of the average doses of rhubarb and jalap fluid extracts. The active principle of jalap, as you know, is a resin. Whether or not this resin remains in solution when the fluidextract is diluted with water is a matter the manufacturer should ascertain. In any event, we suggest that the active ingredients be listed in the order of their importance and that consideration be given to the question of whether or not, under the provision of Section 201(n), some explanation is in order as to the comparatively negligible effect of some of the listed ingredients. \* \* \*"

**CANNED SWEET POTATOES—"YAMS"**

The letter discusses certain questions asked concerning sweet potatoes in the light of the existing standard of identity.

TC-325—September 5, 1940

Correspondent asks certain questions about canned sweet potatoes in the light of the existing definition and standard of identity.

"As to the term 'Yam,' it is our understanding that, from a strictly horticultural standpoint, it is not applicable to any of the varieties of the sweet potato. In fact, Webster's New International Dictionary states that sweet potatoes are often erroneously called yams.

"\* \* \* as you say, the term 'Yam' in certain parts of the country, notably the South, has come to mean, not sweet potatoes in general but certain varieties, and perhaps different ones in different localities. The current identity standard for canned sweet potatoes does not recognize yams as synonymous with sweet potatoes, and the former product name is not, therefore, a proper one. However, until such time as

the practice is shown to be confusing or misleading, we will not offer objection to the name 'Yams' in parentheses following the name 'Sweet Potatoes' when the food conforms to the local conception of 'canned yams.'

"Your second question relates to so-called 'syrup' pack canned sweet potatoes. The standard of course sanctions water as a packing medium and sugar or dextrose or both as a seasoning. We have not had occasion to make any determination of just where seasoning leaves off and 'syrup' begins in canned vegetables \* \* \*. Our understanding of the term 'Ribbon Cane Syrup' is one made by straight evaporation of the juice of the old-fashioned ribbon variety of sugar cane. There was no evidence at the hearing that evaporated cane juice was used as a liquid packing medium, or as a seasoning, for canned sweet potatoes. If we assume, as we must in the absence of more



specific information, that sweet potatoes canned in such a medium would still by their appearance and other characteristics purport to be canned sweet potatoes, it fol-

lows that an amendment to the standard will be necessary to legalize this type of pack."

### DANGEROUS DRUGS

The Administration has not undertaken to make a complete list of drugs which may be dangerous when distributed indiscriminately. Certain drugs have been designated, however, which may not be safe for such distribution.

TC-326 (Supplements TC-54 and TC-165;  
See also TC-350, TC-361)—  
September 5, 1940

Correspondent requests a complete and current list of "so-called dangerous drugs."

"I wish it were possible to comply literally with your request. The Administration has not undertaken to list drugs which may be dangerous when indiscriminately distributed and, as you will readily appreciate, to make a complete list of such drugs would be practically impossible. Not only the composition of drugs but all the surrounding circumstances must be taken into consideration, so that to a considerable extent each drug must be considered on its own merits. The manufacturer or distributor is or should be in a position to reach a determination with respect to his various items of merchandise and, in case of doubt, it is always possible to proceed in the in-

terest of the consumer. The law places the responsibility directly upon the manufacturer and distributor. In an effort to be helpful the Administration has cited as examples a number of such drugs in publishing announcements \* \* \*.

"We have expressed the opinion informally that thyroid, barbiturates, benzedrine sulfate, sulfapyradine, aminopyrine, cinchophen, neocinchophen, sulfanilamide, such anthelmintics as carbon tetrachloride, tetrachlorethylene, aspidium, santonin, chenopodium oil and thymol, products containing therapeutically effective proportions of digitalis, squill, strophanthus or other pharmacologically related drugs, and ointments containing more than 0.2 per cent of mercuric chloride or more than 5 per cent of ammoniated mercury may not be safe for indiscriminate distribution."

### CHLOROBUTANOL

The method of declaration of chlorobutanol as an ingredient may be considered in the light of the function served.

TC-327 (See also TC-357 and TC-385)  
—September 5, 1940

"Under Section 502 (e) of the Act chlorobutanol, which is regarded as a derivative of chloroform, must be declared quantitatively on the label regardless of the amount contained in the preparation. Between its declaration in the title of the preparation and declaration otherwise, I would be inclined to draw the following distinction:

"(1) When chlorobutanol is added for its preservative effect and in amounts commensurate with this purpose, its presence and amount should be indicated on the label but not as a part of the designation.

It would be most informative if such a declaration of chlorobutanol or any other preservative were followed with the parenthetical statement 'preservative.'

"(2) When chlorobutanol is present as an active ingredient contributing to the active pharmacological properties of the preparation and it is present in amounts commensurate with this purpose, it should, in my judgment, be declared as a part of the designation of the article.

"In the light of the above, I think that all manufacturers of bismuth subsalicylate in oil and containing analgesic amounts of chlorobutanol should be asked to include this active ingredient in the name."



### CASCARIN

In the absence of any common knowledge of the significance of the term "cascarin," the Administration has objected to the use of such term as the name of an active ingredient on labels.

TC-328—September 5, 1940

"\* \* \* in the absence of any common knowledge of the significance of the term 'cascarin,' we have objected to the use of this as the name of an active ingredient on the labels of drugs containing such a constituent; moreover, we have refused to offer final comment on labels for drugs contain-

ing this ingredient because we know nothing of its physiological effects. \* \* \* if users of the product want to list the drug by the name 'cascarin,' it would be necessary not only for this Administration but for the public at large to have some source of information as to what the article is."

---

### HORSERADISH

When horseradish is used simply as a spice ingredient it may be included in the designation covering other spices. Where, however, it constitutes a substantial portion of the food, it should be named as an ingredient by its common or usual name.

TC-329—September 5, 1940

Correspondent requests advice on the necessity of declaring horseradish as an ingredient in foods.

"'Horseradish' has been included as a spice for purposes of classification of standards under the old Food and Drugs Act and when used simply as a spice ingredient

could be included in the designation covering other spices or referred to as 'spice' when there are no others employed. However, in such cases where horseradish constitutes a substantial portion of the food, such as for example, in prepared horseradish, it should be named as an ingredient by its common or usual name."

---

### DRUGS DISPENSED ON PHYSICIAN'S PRESCRIPTION

The letter discusses the labeling of drugs dispensed on the prescription of a physician.

TC-330—September 5, 1940

Quoted below are pertinent paragraphs of a letter discussing our understanding of the manner by which compliance with Section 503 (b), from the standpoint of Section 502 (f), can be assured.

"You will note Congress has given consideration to exemptions to drugs dispensed on physician's prescription under Section 503 (b) and in doing so made no exemptions whatsoever from the requirements of Section 502 (f). Regulation (b) (2) under that section, as the regulations now stand, exempts under certain conditions drugs which are to be ultimately dispensed on prescription; but the regulation does not appear to exempt from such requirements the prescriptions filled from such drugs. In other words, there seems to be no exemption of prescriptions from bearing (1) adequate directions for use, and (2) such adequate warnings against probable misuse as may be necessary to protect the user. However, what constitutes adequate directions for use

and adequate warnings against probable misuse on the labels of prescriptions may be much less than what would be adequate on drugs sold under other conditions. Certainly, it may be assumed that the prescribing physician has given orally full directions for use and any warnings against probable misuse that the situation may require. If such transactions are within Federal jurisdiction, either in the District of Columbia or the Territories or elsewhere, then it would seem that the Act requires some directions for use, however sketchy they may be, but that ordinarily it would not require label warnings against misuse because presumably the physician will have given such warnings orally and they will not be necessary on the label to protect the user. However, as I mentioned on a previous occasion, if a drug is dispensed in such form and manner and under such labeling as will enable the user to repurchase the article and continue to use it indefinitely and recommend it to friends, obviously then under such circum-



stances only such directions for use and warnings will be adequate which will in themselves fully protect the consumer.

"It is my understanding that the purpose of Congress in referring to a serial number in Section 503 (b) was to provide a means by which the drug dispensed could be accurately tagged and identified in the event that any question concerning the drug or the prescription arose. This presumes that the dispenser either retain the physician's prescription, as is ordinarily done, or a satisfactory record of the prescriptions. While

we doubt that Congress intended that the physician should fill out his ordinary prescription blank to himself when he dispenses the drug, nevertheless in lieu of this the physician shall retain in his possession a record of the article prescribed and dispensed which is linked to the drug through the serial number, date and name of the physician which appears on its labeling. This record kept by the physician will, we believe, serve as his prescription to himself and satisfy the intent of Congress."

### CALOMEL AND SODA TABLET, N.F.

The statement "Calomel and Soda Tablet, N.F., 1 grain" may create impression that the tablets contain one grain of the combination of calomel and soda. The proposed phraseology "Calomel and Soda Tablet, N.F., Mild mercurous chloride 1 grain" is unambiguous and conforms to Act.

TC-331—September 5, 1940

"Replying to your inquiry \* \* \* we are of the opinion that the statement 'Calomel and Soda Tablet, N.F., 1 grain' may create the impression that the tablets contain one grain of the combination of calomel and

soda. We think your proposed phraseology, namely, 'Calomel and Soda Tablet, N.F., Mild mercurous chloride 1 grain' is unambiguous and conforms to the spirit of the requirement of the Act."

### COAL-TAR COLOR REGULATIONS

The letter discusses the use of different names to describe certified mixture.

TC-332—September 5, 1940

"In reply to your inquiry as to the sale of color mixtures under names other than the name specified on the application for certification, you are advised that no objection will be raised against the use of a limited number of other names to describe a certified mixture. However, these names must be submitted on the application for certification in order that their propriety and ac-

ceptability may be determined by us, a record made of them as being applicable to the mixture in question, and the certificate covering the batch so worded to show that permission has been granted to dispose of the batch, or any portion thereof, under any of the several names proposed. Your distribution records would have to show the quantities sold or distributed under each of the certified names."

### X-RAY APPARATUS—LABELING

The letter discusses the labeling of an x-ray apparatus from the standpoint of Section 502 (f).

TC-333—September 5, 1940

"\* \* \* On the assumption that an x-ray apparatus is sold not in violation of Section 502 (j), the following may be mentioned as an outline of the labeling information which will in our judgment serve to meet the requirements of the Act.

"(1) A permanently attached plate or medallion containing in brief and arresting language a warning that the apparatus is

dangerous and capable of causing x-ray burn and electrical shock, and also bearing a reference to an accompanying booklet. Where an apparatus is so constructed that there is no danger whatsoever of electrical shock, then, in our judgment, reference to shock need not be included.

"(2) In order to fully meet the requirements of Section 502 (f) (2), it may be necessary for the accompanying booklet



to touch upon such items as (a) a description of the machine and its various circuits; (b) some type of graphic representation or set of curves indicating the various output settings necessary to maintain and deliver a known amount of radiation which will not injure either the patient or the operator; (c) instructions concerning the factors affecting the variation in amount of radiation with the use of the machine and the need for recalibration of the machine after a reasonable period of time; (d) reference to precautions necessary for the protection of the patient and operator from the deleterious effects of excessive radiation and a discussion of the procedures necessary to prevent

or detect the existence of such conditions which may be dangerous to health.

"If the manufacturer desires to take advantage of the exemption contained in Regulation (b) (2) under Section 502 (f) (1), the label will be required to bear the 'caution' contained in this regulation. However, the exercise of this exemption does not relieve the manufacturer of the responsibility of providing such information as may be necessary to safeguard against unsafe dosage or method or duration of administration or application. This does not in any way contemplate that the manufacturer will attempt to prescribe for or advise the expert in the treatment of disease.\* \* \*

### DIBUTYL PHTHALATE—COSMETICS

The letter discusses the use of dibutyl phthalate as a solvent for certified color to be used in cosmetic preparations.

TC-334—September 5, 1940

Correspondent asks whether it is permissible to use dibutyl phthalate as a solvent for certified color to be used in cosmetic preparations.

"We assume that you wish to use this substance in the manufacture of a coal-tar color mixture for coloring cosmetic preparations. Such a substance would be classified as a 'diluent' under the coal-tar color regulations. Section 135.06 of these regulations requires that diluents used in the manufacture of coal-tar color mixtures intended for coloring cosmetics be harmless

and suitable for such use.

"This Administration will not refuse certification of EXT D&C colors because of the use of pure dibutyl phthalate as a diluent for such color provided the concentration of color in the mixture is such that the dibutyl phthalate will not comprise a substantial proportion of the finished cosmetic. Final decision in the case of any particular batch of color will, of course, be made when batches \* \* \* containing dibutyl phthalate are submitted to the Administration for certification along with the required accompanying information."

### CERTIFIED COAL-TAR COLORS

A certified coal-tar color may be repacked only by the person to whom certificate was issued, unless the repackaged lot is recertified. The changing of the labels of certified colors is not prohibited if the required information is carried over to the new label and records of the identity of the lot are maintained.

TC-335—September 5, 1940

"\* \* \* you inquire whether a customer who purchases from you a barrel of liquid color, from a batch which has been certified to you under a definite name, can repack this color in smaller containers (presumably under his own label) without recertification providing the customer continues to use the name and other marks of identification for the certified color and keeps accurate records showing the disposition of the quantity purchased.

"We wish to call to your attention Section 135.10 (d) on page 1945 of the Federal Register dated May 9 \* \* \*. This section states that:

"'A certificate shall expire with respect to any coal-tar color covered thereby if the package in which such color was closed for shipment or delivery is opened, unless opened solely for repacking *by the person to whom such certificate was issued.* \* \* \* (Italics added.)

"It is our opinion that this section will make it necessary for your customer to have recertified the liquid color which he purchased from you.

"Neither the Food, Drug, and Cosmetic Act nor the regulations promulgated under its authority prevents changing the labels of certified coal-tar colors. It is, of course, necessary that the original label and the



language placed upon the relabeled product comply completely with the requirements of the statute and the regulations. The original certification number, the quantity of contents statement, and the other required information should, of course, appear upon both labels. If the name which appears upon the package is not that of the actual manufacturer, it should be qualified by appropriate language such as 'Manufactured

for' or 'Distributed by.' Certainly the lot number would be required to appear upon both labels. If relabeling operations are conducted upon certified colors, the firm that changes the label should, of course, maintain adequate records so that the identity of the lot could be established at any time, and the name of the color should not be changed."

### VEGETABLE COLORS—CHLOROPHYLL, ETC.

Administration is not disposed to object to the use in foods of chlorophyll which is free from lead, zinc, arsenic, and copper if inferiority of the food product is not thereby concealed. No investigation has been undertaken to determine the possibility of untoward results from external application of copper chlorophyll.

Administration is not disposed to regard Alkanet Root and Cudbear extract, when purified, as being in category of harmful colors.

TC-336—September 5, 1940

"We have your letter in regard to the use of vegetable colors, principally chlorophyll, in foods and drugs under the new Food, Drug, and Cosmetic Act.

"While under the certification system set up under the new law for colors the Agency assumes the burden of the responsibility for the suitability of coal-tar colors for use in food, drugs, or cosmetics, in the case of other colors that responsibility remains with the manufacturer.

"We certainly have no disposition, however, to object to the use in foods of chlorophyll which is, in fact, free from lead, zinc, arsenic, copper, or other deleterious substances, provided such chlorophyll can be used without bringing about adulteration of the food product by virtue of concealment of inferiority. You suggest that a grade of chlorophyll free from lead, zinc and arsenic but containing copper would

be suitable for use in those applications outlined for the EXT D&C colors under the coal-tar regulations of the new act (drug and cosmetic colors for external use).

"We have undertaken no investigation to determine the possibility of untoward results from the external application of copper chlorophyll. If there is no danger there would appear to be no objection to copper chlorophyll under the conditions as are outlined for EXT D&C colors. In the sale of such a grade of chlorophyll the distributor, of course, has the added responsibility of insuring its restriction to the applications indicated for EXT D&C colors.

"As to the other vegetable colors to which you refer, Alkanet Root and Cudbear extract, we have undertaken no investigations of our own, but have not been disposed to regard these colors, when properly purified, as being in the category of harmful colors."

### POTASSIUM IODIDE

The letter comments on the labeling of a drug product containing potassium iodide as an active ingredient.

TC-337—September 5, 1940

Comment on proposed labeling for a proprietary product containing potassium iodide as active ingredient:

"Inasmuch as bronchial asthma in children is usually on an allergic basis, iodides would not be indicated, and it is therefore suggested that the directions be appropriately revised to indicate that the prepara-

tion is not intended for use by children. Since this preparation is merely palliative in its effect, Section 201 (n) will require, in our opinion that the labeling bear a definite statement which is conspicuous and which clearly indicates that the preparation will have no significant influence in removing the cause of the disease.



"An article of the composition of your product may have some value as a palliative in the treatment of bronchial asthma, but the representation for 'Bronchial Coughs' is entirely too broad and should be appropriately modified.\* \* \*"

"\* \* \* the article is offered as an alternative and relief of paroxysms in hay fever, bronchial and asthmatic conditions. According to the medical consensus, potassium iodide is an expectorant and does not have

properties which will relieve the paroxysms of these conditions. \* \* \* This Administration would have no objection, for an article which contains appropriate proportions of iodides, to some such representation as 'an expectorant for bronchial asthma' provided the labeling conspicuously and clearly declares, in accordance with requirements of Section 201 (n), that this preparation is not a cure for bronchial asthma and will have no influence upon the course of the disease."

### BROMIDE PREPARATION—SEA-SICKNESS, ETC.

In commenting on a proposed label for a proprietary bromide preparation which bore claims for "Sea-Sickness, Train Sickness, and Auto Sickness," Administration states that reference to the use of the article as a sedative would not be misleading if an accompanying statement clearly indicates that the preparation cannot be relied upon to prevent or cure those conditions.

TC-338—September 5, 1940

Comment on proposed label for proprietary bromide preparation, which bore claims for "Sea-Sickness, Train Sickness, and Auto Sickness".

"In these three conditions, reference to

the use of this article as a sedative would not be misleading if an accompanying statement clearly indicates that this preparation cannot be relied upon to prevent or cure these conditions."

### CANNED PIMENTOS—SEEDS

In the case of canned peppers or pimentos, seeds are regarded as inedible and unsuitable. Since the findings of fact on which standard for pimentos or red peppers is based exclude inedible portions, the product would be illegal under any label if it contained seeds.

TC-339—September 5, 1940

Correspondent inquires whether a label "Red Peppers" or "Pimentos" without qualification would be appropriate on a canned product of this material if it also contained the seeds.

"The seeds are not mentioned in the standard of identity for pimentos or red peppers but the findings of fact on which the standard is based provide for the exclusion of 'inedible, undesirable and unsuitable portions.'

"In the case of canned peppers or pimentos we certainly regard the seeds as undesirable and unsuitable portions of the article. We do not believe that the seeds are regarded as a part of the edible product either in the case of the fresh or the canned product by the consuming public. \* \* \* since the findings of fact, in our opinion, do not provide for the inclusion of seeds, canned pimentos or peppers containing the seeds would, in our opinion, be illegal under any label.\* \* \*"

### MONOSODIUM GLUTAMATE

The letter discusses methods of declaring the presence of added monosodium glutamate.

TC-340 (Supplements TC-233)—  
September 17, 1940

Correspondent requests information on the appropriateness of several methods of declaring the presence of added monosodium glutamate in soups.

"While you appreciate that the Federal Food, Drug, and Cosmetic Act gives us no authority to approve labels, we have expressed the opinion that either 'artificial seasoning' or 'artificial flavoring' complies with the requirement of Section 403 (k) of



the Act that the artificiality of this added substance be declared. We have regarded the names 'sodium glutamate' or 'monosodium glutamate' as appropriate when used in addition to the declaration of artificiality. Likewise in addition to the

declaration of artificiality the term 'vegetable protein derivative' is suitable for the substance actually derived from vegetable sources. You appreciate, of course, that it is sometimes obtained from casein, in which event the designation would be different."

### PROCESS CHEESE

Pending the formulation of a standard for process cheese, no action will be taken solely because ingredients are not listed if product is of normal composition.

TC-341—(Rescinds TC-276)—  
October 28, 1940

"You refer to our letter \* \* \* with special reference to process cheese. In this letter we advised you that no standard had been promulgated for process cheese, and that the labels of process cheese would be required to bear a list of the ingredients.

"There have since been certain developments about which I think it is reasonable to advise you. While we had not contemplated issuing a standard, various facts came up since your letter was received which caused this matter to be given further consideration, and decision has now been reached to formulate a definition and standard for process cheese as soon as op-

portunity presents. In this connection, Section 701 (e) requires that a public hearing be held and that the facts brought out at the hearing be given due consideration, which process, as you may realize, is rather time-consuming.

"Pending consideration and issuance of this standard, no action will be taken against process cheese solely on the ground that it does not bear a list of ingredients, if the product is of normal composition. Of course, it should not be adulterated, and it should be labeled in plain and conspicuous manner as 'Process-Cheese,' with indication of variety, and with the name and address of the manufacturer, packer, or distributor, and with a declaration of net weight."

### MARMALADE

Marmalade is not included in standards for preserves and jellies, and must be labeled with statement of ingredients.

TC-342 (Rescinds TC-202)—  
December 10, 1940

"\* \* \* Marmalades not included among definitions and standards for preserves and

jellies effective December 4, 1940. Marmalades under Federal Food, Drug, and Cosmetic Act should therefore be labeled with statement of ingredients."

### OVARIAN SUBSTANCES ADMINISTERED ORALLY

The labeling of ovarian substance and other glandular materials which are essentially inert when administered orally should reveal fact of therapeutic inactivity.

TC-343—December 13, 1940

"Receipt is acknowledged of your letter with reference to 'Capsules Ovarian Substance N.F.'"

"We can readily understand the quandary in which you find yourself with reference to the continued distribution of capsules of ovarian substance. It is a fact, in the light of present scientific knowledge, that it would be impossible to consume a sufficient amount of dried ovarian substance to

obtain the effects of its estrogenic constituents. There is no reliable evidence that any amount of progesterone is effective by mouth.

"On the other hand, we have been informed that there is a demand for this material from some physicians.

"The Food, Drug, and Cosmetic Act was not designed to regulate medical practice and this Administration will not undertake legal action against harmless products



which physicians desire to use as medicaments even though there is no scientific evidence that they are of any value whatever. In the case of products such as dried ovarian substance intended for oral administration, each manufacturer must decide for himself whether he will continue to market under any circumstances a preparation regarded by experts in the field as inert, or will continue to supply any existing demand for the article from physicians who may believe they obtain therapeutic effects from its use. The law does require that the label reveal material facts. We think it is a material fact which

physicians who use such products are entitled to know that there is no scientific evidence that such products when administered orally possess any therapeutic activity. If, notwithstanding such a situation, any physician desires to continue the use of the medicine that is his prerogative so far as the Food, Drug, and Cosmetic Act is concerned.

"\* \* \* The same comment would be made regarding ovarian substance intended for oral administration in any other amount and to any other glandular material which is essentially inert under the conditions of use."

### "STARCH"

Where starch is used in a standardized food, a declaration of the starch need be made only if standard requires it. In case of unstandardized chocolate desserts, "starch" indicates cornstarch to average purchaser, and if other starch is used it is desirable to indicate the type.

TC-344—December 13, 1940

"We have your letter requesting information on the labeling of chocolate desserts containing different kinds of starches. You ask whether it is necessary to list the different starches or if it is sufficient to state 'includes starch.'

"\* \* \* Where starch is used in a food for which a definition and standard has been established in accordance with Section 401 of the Act a declaration of the starch need only be made if the standard definitely requires such declaration. In that event the declaration should be in terms specified in the standard.

"No standards have been established for chocolate desserts. Section 403 (i) (2) requires that in the case of unstandardized food products the ingredients be declared in terms of their common or usual names.

There has as yet been no court interpretation of the meaning of the words 'common or usual name.' It might be argued that the mere word 'starch' is the common or usual name of all starch regardless of its source. On the other hand the courts may hold that the kind of starch is necessarily a part of the common or usual name. We are disposed to believe that the unqualified name 'starch' means cornstarch to the average purchaser and we have no disposition, therefore, to object to the use of the name 'starch' without further indication of the source of the material on chocolate desserts made with cornstarch. Where starch from some other source is employed, however, we believe it would be wise for you to indicate the type of starch actually employed. In this connection we refer you to Section 201 (n) of the statute."

### ARTICHOKES

The letter discusses the manner of declaring the variety of artichokes by common name in ingredient statement of food products.

TC-345—December 18, 1940

Correspondent requests an elaboration of our position on the nomenclature of artichokes. Previous correspondence on this subject had brought out the Jerusalem artichoke and the globe artichoke are not the same, the globe artichoke being the same as the artichoke from the leafy vegetable.

"As we understand your letter, the specific question which you feel has not yet been

answered is: 'Is it necessary to place on the package or box of any artichoke food product the name or variety of artichoke that is used in that food product?'

"The Food, Drug, and Cosmetic Act specifically requires that the label of a fabricated food, among other things, must list the ingredients by their *common or usual names*. Your question then resolves itself into what is the common or usual name of each of the two distinct articles of food, the



leafy vegetable and the tuber. Without questioning your figures as to the increasing consumption in this country of Jerusalem artichoke, the fact remains that the artichoke most familiar to the consuming public is the undeveloped blossom of the leafy artichoke plant, which is commonly and usually referred to simply as 'artichoke'.

"Since, unquestionably, the unqualified term 'artichoke' is the common or usual name for the leafy vegetable, it must be conceded that no authority exists for denying the manufacturers of bakery products containing the leafy artichoke the right to describe that ingredient on labels for such bakery products by the unqualified name

'artichoke'. Applying the same common or usual name doctrine in the case of Jerusalem artichoke, labels of bakery products containing that article as an ingredient would bear the designation 'Jerusalem artichoke', the common or usual name for the tuber, thus accomplishing what you are interested in effecting—a distinction between the common artichoke and the Jerusalem artichoke. Of course, if the Jerusalem artichoke used is a new and improved variation of the Jerusalem artichoke to which the word American has been associated, there is no objection to making a statement to that effect as, for example, 'American type of Jerusalem Artichoke' or 'American (Jerusalem) Artichoke'."

### CANNED APPLESAUCE

A statement of the ingredients of canned applesauce is required.

TC-346—December 18, 1940

Correspondent inquires whether it is necessary to declare the ingredients present in canned applesauce.

"Section 403 (i) (2) of the Federal Food, Drug, and Cosmetic Act requires the declaration of ingredients on the labels of food products which consist of more than one ingredient, with the exception of those products for which standards have been promulgated under the terms of Section

401, or which have been temporarily exempted under the terms of Section 902 (a) (2) pending the formulation of such standards.

"No standard of identity has been promulgated for canned applesauce, nor has this product been temporarily exempted and, therefore, the terms of 403 (i) (2) requiring the declaration of ingredients would apply."

### CREAM

The letter discusses the nomenclature to be used in the labeling of various types of cream in connection with the standards promulgated therefor.

TC-347—December 18, 1940

Correspondent's inquiry concerns the nomenclature to be used in the labeling of various types of cream in connection with the recently promulgated definitions and standards of identity for cream as set forth under Sections 18.500, 18.501, 18.510, 18.511, and 18.515, on page 2443 of the Federal Register of July 2, 1940.

"In the light of the identity definition for the cream class of food under 18.500, the unqualified word 'Cream' may be used as a designation for any one of the specific types of cream defined in Sections 18.501, 18.511 and 18.515. Also, the words 'Whipping Cream' may be used unqualifiedly for

each of the two forms of whipping cream described under Sections 18.511 and 18.515. The only alternative designations permissible are the specific names set forth for each type of cream described in the sections indicated; for example, the cream class of food identified under 18.501 must be labeled either 'Cream' or 'Light Cream' or 'Coffee Cream' or 'Table Cream.' The cream identified under 18.511 must be labeled either as 'Cream' or 'Whipping Cream' or 'Light Whipping Cream.' Similarly, the article defined under 18.515 must be labeled either as 'Cream' or 'Whipping Cream' or 'Heavy Cream' or 'Heavy Whipping Cream.'"



**"DIURETIC PILLS"**

The use of potassium nitrate in medicine has practically been abandoned by physicians. There is considerable doubt as to whether the plant drugs buchu, uva ursi, and broom tops have any diuretic properties.

Administration knows of no disease condition which a layman can diagnose for which a diuretic would constitute an appropriate treatment.

TC-348—December 18, 1940

"We have your letter in which you furnish the formula and proposed label for 'Diuretic Pills.' You request our comment upon both the formula and the label.

"The use of potassium nitrate in medicine has practically been abandoned by physicians. There is considerable doubt as to whether the plant drugs buchu, uva ursi, and broom tops have any diuretic properties. While we are not at the immediate present in a position to adversely criticize the labeling you propose for the formula submitted, we would not be frank if we did not inform you that at the present time the Administration has under investigation the entire field of diuretic drugs and that the information so far collected indicates that

the effect of the pills in question, when taken as directed, would depend largely upon the 'large glass of water' directed to be taken with the pills.

"Aside from the actual effect of the drugs entering into the composition of this article, we know of no disease condition which the layman can himself diagnose and for which he can intelligently prescribe for which a diuretic would constitute adequate or appropriate treatment.

"If the article in question is marketed under the proposed label, the distributor should be informed that it is not improbable that action under the Food, Drug, and Cosmetic Act involving it may be taken in the near or more remote future as the information being collected may justify."

---

**HAIR PREPARATIONS—QUININE—"TONIC"**

The use of the term "quinine" in designation of hair preparations is objectionable, even if the substance is present.

The term "tonic" is misleading when applied to products for use on the hair or scalp.

TC-349—December 28, 1940

"For your information we are enclosing the text of the Federal Food, Drug, and Cosmetic Act. You will be particularly interested in the definition of a cosmetic which is to be found in Section 201 (i) of this Act, and in Chapter VI, which deals with cosmetics.

"It is our view that the various preparations \* \* \* which bear names involving the use of the term 'quinine' are all seriously in violation of the requirements of this statute. Even if quinine were to be added to these mixtures, we do not believe that this would serve to legalize the names. The reason for this opinion will be obvious to you if you will read Regulation (b) under Section 602 (a) of the Act.

"Your letter expresses interest in acquiring

information which will make it possible for you to conduct your business in conformity with the requirements of law. In view of this expression on your part, we are volunteering the information that it is our purpose to immediately begin a program of regulatory actions designed to prevent the use of the word 'quinine' on preparations which have been known as hair tonics. This is because many such preparations contain no quinine, but also because there is no scientific evidence of which we are aware that quinine in such preparations adds in any manner to the effectiveness of the articles. It is also our view that the term 'tonic' as applied to such mixtures is a false and misleading claim, because the articles to which the word is applied do not in fact produce a tonic effect either upon the hair or the scalp."



## DANGEROUS DRUGS

The letter discusses various drugs which are dangerous when sold indiscriminately.

TC-350 (Supplements TC-326; See TC-361)—January 9, 1941

"\* \* \* you ask us to send you a list of drug products banned from over-the-counter sale except on prescription.

"The Food, Drug, and Cosmetic Act which we enforce does not list drug products which may be sold only upon prescription. Section 502 (j) of this statute, however, provides that a drug shall be deemed to be misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

"We are sure you will agree that there are a number of drugs which are in fact dangerous if consumed otherwise than upon the basis of expert advice and under constant supervision. In addition, there are drugs which may safely be distributed to the laity for consumption in small doses, under labeling bearing adequate directions for use and adequate warnings, but which become dangerous drugs for self-medication when administered in larger doses. It is not possible to list all of the preparations which may fall in either category.

"As a guide to the industry and to pharmacists, we have expressed the view that drugs containing significant amounts of such ingredients as cinchophen, neocinchophen, other cinchophen derivatives, cantharides (for internal use), aminopyrine, sulfanilamide, sulfapyridine, thyroid, aconite, benzedrine sulfate (for internal administration), chrysarobin or goa powder, chrysophanic acid, colchicine, colchicum, emetine, phosphides, phosphorus, radium, sulfathiazole, thiocyanates, and the anthelmintics carbon tetrachloride, tetrachlorethylene, aspidium (male fern), santonin, chenopodium oil, and thymol, should not be distributed over the counter for indiscriminate lay use.

"It is our opinion that preparations containing bromides should not be sold directly to the laity if the dosage provided involves the consumption of more than 30 grains per day or more than 15 grains during any 3-hour period.

"The same is true of acetanilid, in the case of medicines that provide a total daily intake of more than 5 grains or more than  $2\frac{1}{2}$  grains during any 3-hour period. For

bromide-acetanilid combinations, we have suggested that preparations for lay use should not provide more than a total daily dose of 15 grains of sodium bromide and 5 grains of acetanilid, or more than  $7\frac{1}{2}$  grains of sodium bromide and  $2\frac{1}{2}$  grains of acetanilid during any 3-hour period. Comparable amounts of other bromide preparations should, of course, be subjected to the same restrictions.

"There is ample scientific evidence to support the view that preparations providing a daily dose of more than 15 grains of acetophenetidin or more than 15 grains of antipyrine are dangerous within the meaning of Section 502 (j) when distributed for indiscriminate lay use. Investigations which are currently in progress strongly suggest the probability that somewhat smaller daily doses of these drugs may likewise be dangerous when consumed indiscriminately. Our regulatory program will, of course, include actions based on sales of acetophenetidin and antipyrine under circumstances providing for a somewhat smaller daily dose if scientific opinion becomes available to establish the illegality of such sales.

"In our judgment, epinephrine in solution of 1 per cent or stronger cannot safely be indiscriminately used, and the same is true of ipecac in daily dosage greater than 10 grains, as well as of strychnine in a daily dose greater than  $1/20$  grain.

"In addition to dangerous drugs comparable to those to which we have referred, there is another class of preparations which cannot legally, in our opinion, be sold without prescription. Section 502 (f) (1) provides that drugs distributed within the jurisdiction of the Federal law must bear adequate directions for use. The regulation under this section exempts drugs from this requirement if they bear the conspicuous statement, 'Caution: To be used only by or on the prescription of a physician.' Drugs bearing this labeling should not be sold otherwise than upon prescription.

"We presume you are well aware of the fact that the regulation of the local practice of pharmacy is the obligation of local authorities. If you wish to acquire information concerning the restrictions imposed by local laws, this may of course be obtained by corresponding with the local officials."



**LAXATIVE WARNINGS—APPENDICITIS**

Laxative warnings should be comprehensive, even though symptoms mentioned may be indicative of conditions other than appendicitis.

TC-351—January 24, 1941

Correspondent asks our opinion of the following proposed warning statement to be used on laxatives, in lieu of that which the Administration has considered unobjectionable, because of his belief that if nausea and vomiting precede abdominal pain appendicitis may be ruled out, but that if abdominal pain is followed by nausea and/or vomiting appendicitis should be suspected:

"Warning: Avoid using in case of abdominal pain followed by nausea or vomiting, or other symptoms of appendicitis.

"Frequent or continued use may result in a dependence on laxatives."

"While pain is not uncommonly the first symptom of appendicitis, we cannot agree

with your statement that the diagnosis of appendicitis may invariably be ruled out if nausea and vomiting precede abdominal pain. We all recognize that the symptoms mentioned may be indicative of conditions other than appendicitis, but in view of the fact that mistakes in the diagnosis of appendicitis as high as 20 per cent are made even by physicians, and in view of the critical nature of appendicitis and the high mortality associated with the use of cathartics in this condition, we believe that it is imperative in the public interest that an arresting comprehensive warning be given on the labeling of cathartics. The warning statement proposed by you does not satisfy these conditions."

**POULTRY FEEDING—VITAMIN D PREPARATIONS**

The announcement of January 22, 1941, addressed "To Manufacturers, Packers, and Distributors of Vitamin D Preparations Intended for Poultry Feeding, and of Ingredients of Such Products," is identified as TC-352.

TC-352—January 22, 1941

To Manufacturers, Packers, and Distributors of Vitamin D Preparations Intended for Poultry Feeding, and of Ingredients of Such Products:

For some time, poultry raisers have used cod liver oil as a source of vitamin D in prevention of rickets in chickens. The users of cod liver oil for this purpose have become familiar with the statement of vitamin D potency in terms of U.S.P. units and are able to utilize such information in compounding poultry feeding rations.

For various reasons there is an increasing variety of products other than cod liver oil appearing upon the market as sources of vitamin D for use in poultry feeding. In some instances the anti-rachitic effectiveness for chicks of the vitamin preparation cannot be measured by the U.S.P. method because of the difference in biological activity for the chick of various forms of vitamin D. Activated ergosterol and blue fin tuna liver oil are vitamin D preparations which do not afford the chick the same degree of protection against rickets as does cod liver oil of equal potency as determined by the U.S.P. method. The Association of Official Agricultural Chemists, recognizing the existence of this condition, adopted a method utilizing chicks for measuring the anti-

rachitic value of vitamin D preparations intended for poultry feeding. The unit used in describing the vitamin D potency is the A.O.A.C. chick unit. By definition, this unit is equal in biological activity for the chick to one unit of vitamin D in U.S.P. reference cod liver oil.

An article which may be used as a source of vitamin D for poultry or an ingredient which may be used to increase the vitamin D content of such a product, labeled only in terms of U.S.P. units, may be misbranded under the Food, Drug, and Cosmetic Act for failure to reveal facts material in the light of such a representation, in accordance with Section 201 (n), if the article does not supply the same number of A.O.A.C. units as U.S.P. units in a given quantity of material.

The label of such a product should reveal the fact that the declaration of the vitamin D potency in terms of U.S.P. units is not a reliable index of its anti-rachitic value for the chick. This may be accomplished by a label statement in connection with the potency declaration to the effect that the vitamin D in the article is in whole or in part unavailable to the chick, or by an additional potency declaration in terms of A.O.A.C. units.



### FOODS EXEMPT FROM INGREDIENT DECLARATION

The announcement of January 21, 1941, "Notice to Food Manufacturers," is identified as TC-353.

TC-353—January 21, 1941

Notice to Food Manufacturers:

Before the Federal Food, Drug, and Cosmetic Act of 1938 became effective the Secretary of Agriculture, acting under the authority of Section 902 (a) (2) of the Act, exempted for periods of about two years a number of food products from the provisions of Section 403 (i) (2) of the Act, which require label declaration of ingredients. The purpose of the exemptions was to afford time for the formulation, promulgation, and effective application of definitions and standards of identity for these products.

The products involved were:

White Bread; Whole Wheat Bread; Milk Bread; Raisin Bread.

Evaporated Milk; Sweetened Condensed Milk; Malted Milk.

Unmixed, Immature Canned Vegetables, properly prepared and with water not in excess of the amount necessary for proper processing, with or without added salt or sugar or both, but with no other added substance.

Unmixed Canned Fruits, properly prepared and in sugar solution of not less than 20° Brix, not in excess of the amount necessary for proper processing, but with no other added substance.

Canned Oysters; Canned Clams; Canned Shrimp (dry and wet pack); Canned Fish Roe.

Sauerkraut; Olives in Brine.  
Cheeses; Oleomargarine; Mayonnaise Dressing.

Fruit Preserves.  
Sweet Chocolate; Sweet Milk Chocolate.  
Lemon Extract; Orange Extract; Vanilla Extract.

Ice Cream; Frozen Custard; Ice Milk; Milk Sherbet; Water Ice or Ice Sherbet.

Nonalcoholic Carbonated Beverages.

It has been impossible to complete the program contemplated within the allotted time. Definitions and standards of identity for several of these foods have been promulgated. Hearings have been held on a number of other products, and promulgation of regulations can be expected within a short time. Work is proceeding as rapidly as possible toward the formulation of proposals for hearing on the remaining exempted products.

No formal extension of the time of exemption for any of these articles is contemplated. However, it will not be the purpose of the Food and Drug Administration to inaugurate action against any of these articles on the ground that they violate the provisions of Section 403 (i) (2) of the Act pending the effective application of definitions and standards of identity or an announcement giving due notice that definitions and standards of identity will not be prescribed.

### COLD PREPARATIONS

The announcement of February 3, 1941, entitled "Notice to Manufacturers of 'Cold' Preparations," is identified as TC-354.

TC-354—February 3, 1941

Notice to Manufacturers of "Cold" Preparations:

For various reasons, one of which has been lack of adequate facilities, the Food and Drug Administration has not in the past given attention to the large number of preparations sold for the treatment or prevention of colds, or for the mitigation of the symptoms of this disease. Henceforth this class of products will be included in the Administration's program of operations.

Present-day medical opinion supports the view that there is no known substance or

mixture of substances which can be relied upon to prevent or cure colds. Surveys of products which now appear upon the market show that many of them make claims involving the treatment or prevention of colds which are not justified by the scientific facts; others exaggerate the effects which the medications will have upon the symptoms.

The Food, Drug, and Cosmetic Act only recently became fully effective. One of its provisions, Section 201 (n), is particularly applicable to those preparations which bear labeling dealing with the symptoms of



colds. This section requires that the labeling reveal any facts which are material in the light of such affirmative representations as the label may make. Under this provision it is the opinion of this Administration that any reference to colds in the label-

ing of a drug should clearly indicate just what the effects of the medicine with respect to this disease condition will be and, if necessary to avoid misunderstanding, just what the limitations of the medication are.

### CALOMEL OINTMENTS—VENEREAL DISEASE

The letter discusses the labeling of an ointment consisting of calomel and petrolatum represented as prophylactic for venereal disease.

TC-355 (Supplemented by TC-397)—  
February 12, 1941

The following comments were recently made to a manufacturer of an ointment consisting of approximately one-third calomel and two-thirds petrolatum:

The Act provides that any mercury derivative present in a drug product shall be declared quantitatively. Your label should also bear a statement that calomel is a derivative of mercury.

The statement "to Prevent Sexual Diseases" is misleading in view of the fact that the product *per se* will protect only against syphilis and then only if properly applied. The cleansing incident to the use of the product will convey some protection against chancroid, lymphogranuloma inguinale, granuloma inguinale, but there will be no protection to speak of against gonorrhea, which is probably the most prevalent of all the venereal diseases. The label should reveal conspicuously that the article will not furnish adequate protection against gonorrhea.

The directions for use should be full and

detailed, because it is a well-established fact that the prophylaxis of syphilis is as much dependent on the technique of administration as it is on the drug administered. The statement "cleanse the organ thoroughly" should be amplified so as to specify with soap and water and to mention by name the extent of the anatomical areas to be washed. The directions should specify the penis, the foreskin, and emphasize the necessity of the retraction of the foreskin so as to cleanse the glans penis and the coronal sulcus. The cleansing should also include the scrotum, the skin of the adjacent parts of the thighs and the abdomen at least up to the navel.

The directions should provide for the rubbing of the salve over all of the parts just considered in the washing. The facts do not justify the claim that the product "will not injure the skin or the most delicate membrane." Further, there should be a warning that patients sensitive to mercury should not use this type of protection.

### CINCHOPHEN—NEOCINCHOPHEN

Cinchophen and neocinchophen are capable of doing serious injury. A warning as to the danger is necessary when they are distributed for prescription use.

TC-356—February 12, 1941

"\* \* \* the data in the possession of this Administration leave no doubt in our minds that cinchophen and neocinchophen are capable of doing serious injury.

"The \* \* \* Act, however, is not intended to regulate the practice of medicine. We have therefore not taken the position that these drugs, when sold under conditions which restrict their use to the filling of prescriptions, are subject to the allegation that they are misbranded because of their danger to health. You must therefore reach a decision for yourself as to whether or not you will recommend the sale of these items and preparations of them for prescription use.

"The responsibility for the adequacy of the warning statement to appear on such

packages must rest with you as the distributor. One manufacturer of these drugs proposed the following warning:

"Warning—This is a dangerous drug which may cause serious or fatal injury, unless consumed under adequate and continuous medical supervision. It may cause acute yellow atrophy and cirrhosis of the liver. Caution: Therefore it is to be used only by or on the prescription of a physician; and never otherwise."

The Administration did not offer adverse comment on this proposed warning.

"If, in the future, the accumulating knowledge concerning the toxicities of these products makes them appear to be in violation of Section 502 (j), in that they are dangerous for use under any form of labeling, the above comments would be modified accordingly."



**CHLOROBUTANOL**

The letter discusses the labeling of drugs containing chlorobutanol when used solely as preservative or analgesic in preparations containing one or more other active ingredients intended for parenteral use only.

TC-357 (Substitute for TC-327;  
See TC-385)—April 17, 1941

"Replying to your inquiry regarding the classification of chlorobutanol as a chloral derivative in the proposed regulations under Section 502 (d), your attention is called to the proposed amendments to the general regulations under this section, as given in the second column of page 680 of the Federal Register for January 30, 1941, (relating to chlorobutanol when used solely as an analgesic and/or preservative in a quantity not more than 3.0 per cent in preparations containing one or more other active

ingredients intended for parenteral use only.)

"We are disposed to regard the declaration of chlorobutanol and other substances when used solely as preservatives and/or analgesics under the above limitations as required by Section 201 (n) of the Act rather than as a requirement of Section 502 (d) or (e). Accordingly, we are not inclined to insist that the parent substance be mentioned in connection with the declaration of chlorobutanol under the circumstance outlined in your letter."

**"IMITATION STRAWBERRY JAM"**

A mixture of strawberries, apple juice, and sugar cooked to consistency of jam and conforming in composition to a mixture of 40 per cent strawberry jam and 60 per cent apple jelly will simulate the appearance and flavor of a strawberry jam and should be labeled as an imitation strawberry jam and contain statement of ingredients as required by Section 403 (i) (2).

TC-358—April 17, 1941

Correspondent has inquired regarding the labeling, under the Food, Drug, and Cosmetic Act, of a mixture of 40 per cent strawberry jam and 60 per cent apple jelly, and a mixture of 85 per cent apple jelly and 15 per cent strawberry jam.

"A mixture of strawberries, apple juice, and sugar cooked to the consistency of a jam and conforming in composition to a mixture of 40 per cent strawberry jam and 60 per cent apple jelly will simulate the appearance and flavor of a strawberry jam and, in our opinion, should be labeled as an imitation strawberry jam under Section 403 (c) of the Act and should

also be labeled with a statement of the ingredients, as required under Section 403 (i) (2). A suitable declaration of ingredients would be 'Sugar, apple juice, strawberries,' also 'pectin and acid,' if these latter ingredients are used.

"Likewise, we are of the opinion that your mixture of 85 per cent apple jelly and 15 per cent strawberry jam is an imitation strawberry jam under the provision of the Act referred to above and should likewise be named 'Imitation Strawberry Jam,' the name to be followed by a statement of the ingredients in the order of their predominance by weight."

**"PURE FOOD COLOR"**

The term "Pure Food Color" is inappropriate when applied to mixture of certified coal-tar color and diluent since it is ambiguous and may mislead.

TC-359—April 22, 1941

Correspondent asks whether it is permissible to use on the label of coal-tar dyes which have been certified by this Administration the legend "Pure Food Colors."

"While we have not taken any action under the Food, Drug, and Cosmetic Act against certified coal-tar color mixtures

labeled 'Pure Food Color' the consideration we have given to the matter since receipt of your inquiry leads us to the conclusion that such a designation is not free from objections. One objection is that a certified color mixture, such as you describe, is not in fact a pure food color but contains only a small proportion of dye mixed



with large amounts of diluent. It is our conviction that the designation 'Pure Food Color' is, to say the least, ambiguous.

"Since such a designation may be misleading and deceptive, we advise against its

use and recommend in place of it the informative 'Certified Food Color,' assuming of course that the mixture is in fact certified."

### ACONITE ROOT—GELSEMIUM—"LAXATIVE COLD CAPSULES"

When taken in therapeutic quantities, aconite root and gelsemium may exert toxic effects and thus violate Section 502 (j).

The name "Laxative Cold Tablets" creates a misleading impression.

TC-360—April 24, 1941

"The formula which you now submit contains aconite root and tincture of gelsemium. When taken in therapeutic quantities, these two ingredients are particularly capable of exerting toxic effects. Therefore, in answer to your general inquiry whether this formula violates any provision of the Food, Drug, and Cosmetic Act, it is our opinion that an article of this composition when taken as directed may violate Section 502 (j) \* \* \*. In view of the toxic properties of gelsemium and aconite, you may wish to give consideration to their deletion from this formula.

"The name of this article (\* \* \* Laxa-

tive Cold Capsules) creates the misleading impression that its sole effect will be that of a laxative, whereas it contains ingredients possessing actions other than that of a laxative. The word 'Cold' appearing as it does in the name of the product, may also be misleading in that it creates the false impression that this article is a specific for colds, whereas its therapeutic efficacy is limited to the temporary relief of some of the symptoms which may accompany a cold. In our opinion, the labeling should be revised to indicate clearly and conspicuously just what the effects of this preparation will be with respect to the symptoms of a cold."

### DANGEROUS DRUGS

The information sheet entitled "Information Concerning Drugs that Should Be Sold Only To or Upon the Prescription of Physicians, Dentists, or Veterinarians," and dated April 24, 1941, is identified as TC-361.

TC-361 (Replaces TC-54, 165, 326, and 350; See also TC-366, TC-373)—April 24, 1941  
Information Concerning Drugs that Should be Sold Only to or upon the Prescription of Physicians, Dentists, or Veterinarians.

The Administration has received numerous requests from drug manufacturers, retail and wholesale drug associations, and others, for a list of those drug products which it considers dangerous when sold otherwise than on the prescription of a physician, dentist, or veterinarian licensed by law to administer drugs.

In answer to such requests, the Administration has pointed out that the Food, Drug, and Cosmetic Act places upon the manufacturer and the distributor the responsibility for properly safeguarding the marketing of drugs which may be dangerous to the purchaser if distributed without restriction. Obviously, it is impossible to list all drugs which may be dangerous since not only the compositions but also the directions for use and the conditions in

which their use is recommended may have a very definite bearing on the question of safety or danger. As examples of drugs which are considered dangerous when distributed for use otherwise than on prescription, the following have been mentioned:

- Aconite
- Aminopyrine
- Barbiturates
- Benzedrine sulfate (for internal use)
- Cantharides (for internal use)
- Chrysarobin or goa powder
- Chrysophanic acid
- Cinchophen, Neocinchophen, and other cinchophen derivatives
- Colchicine
- Colchicum
- Emetine
- Phosphides
- Phosphorus
- Radium
- Sulfanilamide
- Sulfapyridine
- Sulfathiazole



Tansy, Tansy Oil

Thiocyanates

Thyroid

The anthelmintic drugs:

Carbon tetrachloride

Tetrachlorethylene

Male fern (*aspidium*)

Santonin

Wormseed Oil (*chenopodium* oil)

Thymol

It is our opinion that preparations containing bromides should not be sold without prescription if the dosage provided involves the consumption of more than 30 grains per day or more than 15 grains during any 3-hour period.

The same is true of acetanilid, in the case of medicines that provide a total daily intake of more than 5 grains or more than  $2\frac{1}{2}$  grains during any 3-hour period.

For bromide-acetanilid combinations, we have suggested that preparations for lay use should not provide more than a total daily dose of 15 grains of sodium bromide and 5 grains of acetanilid, or more than  $7\frac{1}{2}$  grains of sodium bromide and  $2\frac{1}{2}$  grains of acetanilid during any 3-hour period. Comparable amounts of other bromide preparations should, of course, be subjected to the same restrictions.

There is ample scientific evidence to support the view that preparations providing a daily dose of more than 15 grains of acetophenetidin or more than 15 grains of antipyrine are dangerous within the meaning of Section 502 (j) when distributed for indiscriminate lay use. Investigations which are currently in progress strongly suggest the probability that somewhat smaller daily

doses of these drugs may likewise be dangerous when consumed indiscriminately. After public notice, our regulatory program will, of course, include actions based on sales of acetophenetidin and antipyrine under circumstances providing for a somewhat smaller daily dose if scientific opinion becomes available to establish the illegality of such sales.

In our judgment, epinephrine in solution of 1 per cent or stronger cannot safely be indiscriminately used, and the same is true of ipecac in daily dosage greater than 10 grains, as well as of strychnine in a daily dose greater than  $1/20$  grain.

We have also expressed the opinion that products containing therapeutically effective proportions of digitalis, squill, strophanthus, or other pharmacologically related drugs may not be safe for indiscriminate distribution.

It has been our experience that manufacturers of such drugs as have been mentioned have taken advantage of the regulation permitting omission of directions for use and substitution of the so-called "prescription legend." Where the legend "Caution: To be used only by or on the prescription of a Physician (Dentist, or Veterinarian)" appears upon the package in lieu of directions for use, it is the obligation of the retailer to observe the injunction that the article be dispensed only upon prescription.

The fact that the Federal law is applicable to the distribution by retailers of drugs which have been in interstate commerce in no way restricts the enforcement of State and local acts relating to the sale of drugs or the practice of pharmacy.

## DEVICES—LABELING

The letter discusses the necessary warnings to be declared on devices, the distinction between Section 502 (f) (1) and Section 502 (f) (2), and the distinction between "Directions for Use" and "Dosage Directions."

TC-362—July 7, 1941

Correspondent asked for comment on suggested warnings with reference to selling certain therapeutic devices to the laity.

"(1) If a device is sold to the laity without the prescription of a physician, its label or labeling must bear all of the required information, including adequate directions for use as well as such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or

application, in such form and manner as are necessary for the protection of the users.

"(2) If a device is sold only to physicians or on a physician's prescription, the manufacturer can avail himself of the exemption under Section 502 (f) (1). In our judgment there is nothing in either Section 502 (f) (1) or (2) which will relieve the manufacturer of a device for which adequate directions for use are not commonly known from the obligation of providing adequate directions for using or operating the machine, either in the labeling or otherwise.



You will note that the Act provides no exemptions from the requirements of Section 502 (f) (2).

"(3) The statement 'Caution: To be used only by or on the prescription of a ——— (the blank to be filled in by the word 'Physician,' 'Dentist,' or 'Veterinarian,' or any combination of such words)' cannot be regarded as adequate warning in terms of the requirements of Section 502 (f) (2) for all devices distributed for use by or under a physician's direction. In our judgment, warning statements must be specific and of such a character as to fulfil the purpose for which this section of the Act is intended. Adequate warnings as intended under Section 502 (f) (2) must appear in any case, regardless of the type of distribution. Such warnings should include information against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

"(4) In conclusion it should be clearly understood that the Administration does not contemplate that a manufacturer will attempt to prescribe or advise the expert in the treatment of disease. In this regard it may be well to point out the distinction between 'Directions for Use' and 'Dosage Directions.' A discussion of 'Directions for Use' may cover such subjects as (a) assembly of the apparatus, (b) proper testing after assembly and before use, (c) proper care of apparatus between intervals of use, etc., (d) the mechanics of operating the device. A discussion of 'Dosage Directions' in the case of an apparatus bearing the legend 'Caution: To be used only by or on the prescription of a physician' would appear in our judgment to be unnecessary, as it is assumed that the attending physician had adequately instructed the patient or attendant. When a device is intended for distribution by or on the prescription of a physician, such a device may be considered to be misbranded if it is sold without a prescription of a physician, dentist, or veterinarian."

### "VITAMIN B COMPLEX"

The letter discusses the use of the term "vitamin B complex" in the trade names of preparations.

TC-363—July 7, 1941

Correspondent requested a discussion on the views of the Administration concerning the use of the term "vitamin B complex" in the trade names of preparations.

"It is quite apparent from the literature that the term 'vitamin B complex' has no specific meaning. The term has been applied, for example, to a particular preparation demonstrated to contain all of the water-soluble vitamins necessary for growth and reproduction of the rat. The term has also been widely applied to the group of water-soluble vitamins, other than vitamin C, that may be required by several species of animals, including factors which have not been identified. There is evidence that all components of the vitamin B complex are not equally essential to different species. For example, it appears that nicotinic acid, which is essential for man, is not necessary in the ration of the rat or the chicken. Furthermore, new discoveries in this field, which have developed so rapidly, may require new interpretations of the term and impose different labeling requirements.

"When these facts are considered in connection with the provisions of the Food,

Drug, and Cosmetic Act which proscribe labeling which is false or misleading in any particular, it would seem the part of wisdom to avoid the use of the term 'vitamin B complex' as the name for a product, though we will not for the time being take exception to the use of this term providing the product to which it is applied furnishes in the recommended daily intake consequential amounts of the vitamins of the B complex known to be necessary in human nutrition and demonstrable quantities of all other components of the vitamin B complex, including those which have not been identified. In other words, a product which is designated 'vitamin B complex' should furnish consequential amounts of thiamine, nicotinic acid, and riboflavin when considered in the light of the recommended doses to be consumed, demonstrable amounts of pantothenic acid, pyridoxine, and para-amino benzoic acid and other components of the vitamin B complex which have not been identified. The product, of course, would be inappropriately designated if it were called 'a natural vitamin B complex' if the entire vitamin ingredients were not those obtained from natural sources. Other



requirements of the law, of course, make it necessary that the common names of the ingredients from which the product is fabricated be declared conspicuously upon the label.

"We cannot escape the conclusion that the term 'vitamin B compound' will be assumed by the ordinary purchaser to be

synonymous with the term 'vitamin B complex.' Its use, therefore, for products which do not meet the conditions described above would constitute misbranding.

"Final regulations under Section 403 (j) will, of course, provide certain definite requirements applicable to many of the products contemplated in this letter."

### ABSORBENT COTTON

The descriptive terms "universal" and "general purpose" are of questionable propriety for absorbent cotton which is not sterilized.

TC-364—July 7, 1941

"Your product is designated as a 'general purpose bleached cotton' and is further labeled as for 'universal use.' It also carries the statement 'Not to be confused with "Purified (Absorbent) Cotton" U.S.P.' Since this cotton is not sterilized, the use of the terms 'universal' and 'general purpose' is of questionable propriety, because it may not properly be used either univer-

sally or generally. We note your statement that this item is restricted to hospitals. We are not disposed at this time to raise the question of the packaging requirements of the Pharmacopoeia for cotton conspicuously labeled as 'Not Sterilized' and otherwise conforming to the requirements of the law, particularly if its fiber length meets the requirement of the Pharmacopoeia.\* \* \*

### ALKALOIDS IN CIGARETTES

The alkaloids present in a product intended to be burned and the smoke inhaled may be expressed in terms of range, preferably by weight per unit, as weight of stramonium alkaloid per cigarette.

TC-365—July 7, 1941

"We have your letter inquiring as to whether or not it will be permissible to declare stramonium alkaloids in cigarettes in which the main ingredient is powdered stramonium leaves in terms of a range of 0.3 to 0.4 per cent.

"In ordinary circumstances where stramonium preparations are to be so administered that the patient receives a definite amount of stramonium, the content of alkaloid should be stated in definite terms. In the case of cigarettes and powders intended to be burned—the smoke to be inhaled—it

is obvious that much of the alkaloid will be destroyed and the alkaloid, or the products of the destructive distillation of the alkaloid, will be inhaled only in part. For this reason an exact statement of the stramonium alkaloid present does not have the significance which otherwise would be attached to it. We are not disposed to object to the declaration of stramonium alkaloids in such preparations in terms of a range. Instead of the percentage present, we think the declaration should be in terms of the weight of the alkaloids per cigarette or other unit."

### DANGEROUS DRUGS—VETERINARY USE

Drugs regarded as dangerous when indiscriminately distributed for human use would not necessarily require a prescription when labeled for use solely in the treatment of lower animals. When not dangerous when so used, the labels should give adequate directions for use and plainly show that the drug is for animals only.

TC-366 (See also TC-361, TC-373)—  
July 7, 1941

"Your letter raises a question which does not appear to be covered specifically in the

notice which recently issued in regard to potent drugs (TC-361), that is, drugs in this list which may be intended for and actually used in the treatment of domestic



animals. This list was intended to cover particularly those drugs which might be distributed to the public on the presumption that they would be for personal use.

"\* \* \* It was not our purpose to indicate that the Food and Drug Administration considers that the drugs named, when labeled for use solely in the treatment of lower animals, would necessarily require a prescription. Where these drugs are intended for treatment of diseases of the

lower animals, and are not dangerous when so used, the labels should give adequate directions for such uses, and these directions should show that the drug is for animals *only*, with some such plain and conspicuous label as 'Sulfanilamide Veterinary.' It is understood, of course, in every case that any of these drugs labeled as treatments for animals are to be so used and not diverted for administration to human beings."

### "ANTACID"—"EXPECTORANT"—"DIURETIC"

The terms "antacid," "expectorant," "diuretic" and others have therapeutic indications under Regulation (b) (4) of Section 502 (f) (1), which probably require their elimination. Administration will not presently object, however, in view of fact that a general manufacturing practice of so designating such drugs is prevalent.

TC-367—July 9, 1941

"We have considered very deliberately the question presented in your letter, whether the use of terms such as 'diuretics,' 'expectorants,' and 'antacids' would be considered as representations within the meaning of Regulation (b) (4) of Section 502 (f) (1) of the Act.

"It is difficult to escape the conclusion that such terms, and many others similar to them popularly used in the designation of classes or types of drugs, do have therapeutic indications either direct or implied. A strict interpretation is to be expected of the requirements imposed as conditions precedent to an exemption. The regulation probably would require the elimination of the use of these words on the ground that they were prohibited representations.

"An administrative attitude based on this conclusion does not deprive the manufac-

turer of the privilege of their use. If such designation is essential to satisfactory labeling and merchandising, this can be met by providing directions for use instead of employing the legend 'Caution: To be used only by or on the prescription of a physician,' a precautionary measure which from considerations of health can scarcely be said to be imperative in the sale of preparations ordinarily included in the categories of expectorants and antacids.

"In view of the fact, however, that a general manufacturing practice of so designating these classes of drugs is prevalent in virtually all drug manufacturing establishments in the country, the Administration, for the present, will not object to the use on the label of such terms on the ground that they are prohibited representations within the meaning of the regulation."

### STRAMONIUM—BELLADONNA

When stramonium is substituted for belladonna in products whose labels declare the presence of belladonna, the labels should be conspicuously corrected to show the change. The term "Belladonna-like Alkaloids" does not meet the common name requirement.

TC-368—July 9, 1941

"We have your letter regarding the problems which are arising by reason of the shortage of belladonna.

"We appreciate the unforeseen difficulties which this situation is creating. While the Administration, as you know, has no authority to sanction misrepresentations on labeling, we will not be disposed to criticize adversely the use of appropriate additional

labeling, with tins already lithographed carrying a declaration of belladonna, to show that stramonium has been substituted for belladonna. We think this information should be conspicuously displayed, preferably on the outside of the package. Where it is at all possible, it would be preferable to use stickers to cover over the declaration of belladonna and indicate that stramonium is present. We appreciate that in the case



of some lithographed tins this is not practicable.

"With reference to the use of the term 'Belladonna-like Alkaloids' as the common name of an extract of either belladonna or stramonium, thus allowing a choice at any particular time, we are of the opinion that this would not conform to the requirement of Section 502 (e) that the common or

usual name of the ingredient be stated. Perhaps atropine or an atropine salt or a suitable mixture of mydriatic alkaloids might be used in the formula in the place of belladonna or stramonium or their extracts. Under these circumstances it would, of course, be immaterial as to the source of the alkaloids."

### DRUGS—EXEMPTION

The exemption permitting the shipment of unlabeled drugs requires the existence of an agreement in which the specific labeling to be used is set up.

TC-369—July 9, 1941

"Regarding the agreement between you and your customers, justifying the shipment of drugs in an unlabeled condition, your attention is directed to Regulation (a) (2) under Section 503 (a) of the Food, Drug, and Cosmetic Act and particularly to the reference to 'specifications for the \* \* \* labeling \* \* \* of such drug \* \* \*.'"

We do not think suggestions by the shipper regarding the form of label, or even demands by him on the consignee, suffice to meet this condition on which exemption from labeling is authorized. Our interpretation of the regulation is that there must be an agreement in which the specific labeling to be used is set up."

### MAGNESIUM CITRATE SOLUTION

A solution of magnesium citrate is not U.S.P. quality if water other than distilled water is used.

TC-370—July 9, 1941

"Since the *United States Pharmacopoeia* specifically states that distilled water is to be used for the preparation of citrate of magnesia solution, if water other than distilled water is used, the resulting drug

would differ from the official preparation in quality. Such an article should be conspicuously labeled to show that it does not conform to the official specifications and the nature of the deviation."

### MILD MERCURIAL (BLUE) OINTMENT

Blue (mild mercurial) ointment, when sold to laity, is unsafe treatment of any condition other than pediculosis pubis (crabs). Its labeling must bear adequate directions and warnings.

TC-371—July 9, 1941

Correspondent requested comment on label for Mild Mercurial Ointment (Blue Ointment) U.S.P.

"It is our opinion that the label of a 30 per cent mercurial ointment should bear adequate directions and warnings. We do not believe that such an ointment is a safe lay remedy for possibly any conditions other than pediculosis pubis, and it certainly is an irrational therapy for any condition but the one mentioned. We believe, therefore, that the directions for use should be comprehensive enough so that the ordinary layman could use this preparation.

We believe that there should be a statement to the effect that the ointment by itself is not capable of killing the nits, and that accessory means must be employed to eradicate these. Directions should include statements to the effect that the ointment must be applied to the hairy areas adjacent to the pubis, especially in the male. However, there should be warnings against the application of this ointment to areas greater than those indicated because of the dangers of systemic absorption. There should also be warnings against the local irritative effects that blue ointment is prone to cause and a statement to the effect that if irrita-



tion occurs, the use of the ointment should be stopped.

"This opinion is based on our present knowledge. In all fairness to you we should like to point out that we are making a comprehensive survey concerning the use of externally applied mercurial preparations

and blue ointment in particular, endeavouring to determine whether as potent an article as this can be used safely by the layman. We feel that a cautious attitude should be taken in regard to the safety of such an article in view of its therapeutic irrationality."

### ARSPHENAMINE—DIRECTIONS FOR USE

Ampuls of arspenamine and other drugs not usable for self-medication may bear directions for use without being considered dangerous.

TC-372—July 9, 1941

"Particular consideration has been given to the status of ampuls of arspenamine and other drugs falling into the same class, in the light of the new regulations promulgated in pursuance to the provision in Section 502 of the Act, which, in effect, directs the Administrator to promulgate regulations exempting drugs from the requirement that the labeling bear adequate directions for use, where such directions are not necessary for the protection of the public health.

"Regulation (b), promulgated on April 10 and published in the Federal Register for April 15, 1941, listed certain conditions under which directions for use may be omitted from the labelings of drugs. One of these, numbered (3), reads as follows: 'The label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ———" or "Caution: To be used only by a ———," the blank to be filled in by the word "physician," "dentist," or "veterinarian," or any combination of two or all of such words, as the case may be.'

"The principal purpose of the authorized exemption of which this condition is a part was to permit the distribution of drugs which may be useful in the hands of practitioners but which would be dangerous and

therefore violative of Section 502 (j) of the Act if indiscriminately marketed with directions for use for self-medication.

"In the case of drugs which are to be administered parenterally the danger of their use for self-medication, so far as we are aware, is practically nonexistent. If they are safe in the hands of the professions and are not suitable for oral use, there would be no health hazard involved in the distribution of these drugs with labeling including adequate directions for use addressed to members of the professions. If the manufacturer does not elect to take advantage of the exemption for the omission of adequate directions for use, he need not do so, provided such products will not be regarded as dangerous to health and that the directions which accompany the article are adequate. The Administration, therefore, will not object to inclusion of adequate directions for use in, and the omission of the so-called prescription legend from, the labeling of drugs suitable for parenteral use only. Such preparations would include ampul solutions generally and arspenamine and neoarsphenamine in particular. This does not apply to classes of drugs that are primarily intended for parenteral administration but may nevertheless be used orally."

### SULFANILAMIDE—VETERINARY USE

The sale of sulfanilamide tablets for veterinary use is permissible if the tablets are properly labeled.

Sulfanilamide is not effective for distemper or blacktongue of dogs, and sulfanilamide tablets labeled for these conditions will be regarded as misbranded.

TC-373 (Supplements TC-366)—  
August 26, 1941

"We have your letter \* \* \* which inquires whether or not it is permissible for druggists to sell sulfanilamide tablets over the counter for the purpose of treating diseases of lower animals such as distemper

in dogs, sore mouth, etc.\* \* \*

"While this Administration has expressed the opinion that sulfanilamide is too dangerous for use in self-treatment and that its indiscriminate sale for such purpose after receipt in interstate commerce involves violation of the Federal Food, Drug,



and Cosmetic Act, we would not be inclined to regard its sale under proper labeling, solely for veterinary use, as subject to the same restriction. In order to obviate the possibility of any misunderstanding, we are of the opinion that sulfanilamide sold for veterinary use should be conspicuously designated as 'Veterinary Sulfanilamide Tablets' or 'Sulfanilamide Tablets for Veterinary Use Only,' all this wording being in type of the same size and style and prominently displayed. In addition, definite directions for administration to lower animals and adequate warnings with respect to untoward effects should be supplied. Of course, the labeling should not only contain no recommendation for use by

humans, but should definitely state that the article is not for use by humans.

"Incidentally, sulfanilamide has not been found effective for the treatment of distemper of dogs or of blacktongue, frequently referred to as sore mouth. Blacktongue is definitely known to be associated with a nutritional deficiency, and can be effectively treated with an adequate diet. We would regard as misbranded, in violation of the law, sulfanilamide tablets labeled as a treatment for distemper or sore mouth of dogs. In fact the field of usefulness of sulfanilamide in diseases of lower animals is quite restricted so far as present knowledge is concerned."

### PROPYLENE GLYCOL

In the amounts normally used in food products, propylene glycol is not to be regarded as a harmful ingredient.

TC-374—December 10, 1941

The correspondent inquires as to whether or not there has been any change in the attitude of this Administration as to the use of propylene glycol in flavorings since that expressed in a previous letter.

"Since our earlier correspondence with you on this subject, our Division of Pharmacology has conducted extensive investigations which will be published on both the acute and chronic toxicity of propylene

glycol and, in addition, we have been advised of similar investigations conducted in other laboratories. Careful review of all of the available results does not show that, in the amounts normally used in food products, propylene glycol is to be regarded as a harmful ingredient. We, therefore, will not interpose objection to the proposed use of this substance to replace glycerin or other solvents in food products from the standpoint of the requirements of the Federal Food, Drug, and Cosmetic Act."

### "PRESCRIPTION LEGEND—NON-DANGEROUS DRUGS—LIVER PREPARATIONS"

While the regulation under Section 502 (f) does not specifically prohibit the appearance of both the caution statement and directions for use, the Administration has discouraged such practice. If a preparation intended for oral use would not, *per se*, be dangerous, the Administration would regard as compliance with Section 502 (f) (1) a statement, in connection with the average dose, that appropriate dosage and frequency and duration of administration for each patient should be ascertained by a physician.

TC-375—December 10, 1941

"Receipt is acknowledged of your recent letter regarding the labeling of your preparations of liver.

"Section 502 (g) of the Food, Drug, and Cosmetic Act defines as misbranded any official drug which is not packaged or labeled as prescribed in an official compendium. Since the Pharmacopoeia specifies that Solution of Liver (Liquid Extract of Liver) and Purified Solution of Liver (Parenteral Solution of Liver) shall bear upon their labels a statement of the average

dose, such statement should appear thereon. In the light of present-day scientific opinion the statement of average dose which you propose will, we believe, satisfy this requirement.

"The regulation under Section 502 (f) states the conditions under which adequate directions for use need not appear upon labels. One of these is that the label bear the statement 'Caution: To be used only by or on the prescription of a physician,' and that no representation appear in the labeling of such drug or device with respect to the



conditions for which it is to be used. While the regulation does not specifically prohibit the appearance of both the caution statement and directions for use, we have attempted to discourage such practice so that the appearance of the legend on the label would constitute notice to the pharmacist that over-the-counter sale of the article would be illegal.

"If your preparation intended for oral use would not, *per se*, be dangerous, the

Administration would regard as constituting compliance with Section 502 (f) (1) of the Act a statement upon the label, in connection with the statement of the average dose, to the following effect:

"'Notice to the purchaser: Appropriate dosage and frequency and duration of administration of this preparation for each patient' should be ascertained by a physician.'"

### NOTICE TO MANUFACTURERS OF GLANDULAR PREPARATIONS

Glandular preparations which are devoid of active constituents, or which are inactive orally, are misbranded unless reference to the presence of glandular constituents is accompanied by a statement that the article does not contain any known therapeutically useful constituent of the glands mentioned.

TC-376, December 10, 1941 (Supplements TC-13)—December 4, 1941

On December 1, 1939, in a notice addressed to manufacturers of preparations of ovary, this Administration expressed the opinion that preparations of ovary recommended for oral administration which are devoid of the known active constituents of that gland are adulterated and misbranded if labeled in a manner implying that such active constituents are present.

The same principle is applicable, of course, to preparations, recommended for oral use, of corpus luteum and "ovarian residue"; and to preparations of various other glands including orchic, suprarenal, and pituitary. In particular there is no scientific evidence that preparations of the named glandular substances, except concentrated estrogenic extracts of ovaries, exhibit any physiologic or therapeutic effects when administered through the gastrointestinal tract. Some of the preparations of these glands intended for parenteral administration also have been found devoid

of any significant activity. Any such inert preparation is regarded as misbranded unless reference upon its labeling to the presence of such glandular constituents is accompanied by a forthright, conspicuously displayed statement to the effect that the article does not contain any known therapeutically useful constituent of the gland or glands mentioned.

Further, there is no scientific evidence that prostate, pineal, and mammary contain any therapeutically or physiologically active constituents. The labeling of articles purporting to be preparations of these glands should, in the opinion of the Administration, bear conspicuously displayed statements to this effect.

Section 201 (n) of the Federal Food, Drug, and Cosmetic Act requires, in effect, the revelation of such material facts. Labeling which merely disclaims responsibility of the manufacturer for activity of an article is not regarded as complying with this provision of the law.

### MONOCHLORACETIC ACID

Monochloroacetic acid constitutes an adulterant in food, no matter in what amount added.

TC-377—December 29, 1941

"In approaching the question of whether a substance like monochloroacetic acid may be employed in a food product shipped within the jurisdiction of the Food, Drug, and Cosmetic Act we must be guided, of course, by the precise terms of the statute. The applicable provisions of the Act are Sections 402 (a) (2) and 406 (a). Section 402 (a) (2) states that

'A food shall be deemed to be adulterated if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406.'

"The pertinent portion of Section 406 (a) reads:

'Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof



or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of Section 402 (a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of Section 402 (a).'

"Two questions must be answered as a preliminary to determining the application of the Act to the use of monochloroacetic acid as a food and beverage preservative: (a) Is monochloroacetic acid an added poisonous or added deleterious substance? (b) If so, is it required in the production of the food or can its use not be avoided by good manufacturing practice?

"Our experiments on monochloroacetic acid show that when administered to experimental animals such as rats, mice, and guinea pigs, its acute toxicity is comparable to that of such recognized poisons as bichloride of mercury (corrosive sublimate), phenol (carbolic acid), and strychnine. Its acute oral toxicity is one-half that of bichloride of mercury when administered to rats, one-third when administered to mice, and one-eighth when administered to guinea pigs. It is five times as toxic as phenol when administered to rats. It is one-eighth as toxic as strychnine when administered to rats, and one-half when administered to guinea pigs. We cannot escape the conclusion that a substance having an acute oral toxicity so closely comparable with these definitely recognized poisons must itself be regarded as a poisonous or deleterious substance. The answer to question (a), therefore, is in the affirmative.

"It then becomes necessary to determine, in answer to question (b), whether this

poisonous or deleterious substance is required in the production of foods or beverages or cannot be avoided by good manufacturing practice. On this it is hardly necessary to do more than point out that the product has been proposed quite recently as a food and beverage preservative and that other means of preservation which do not involve the addition of a poisonous or deleterious substance are available to manufacturers. Quite evidently its use can be avoided in good manufacturing practice.

"It follows, therefore, that no obligation is imposed upon the Administrator to promulgate regulations limiting the quantity of monochloroacetic acid under the terms of Section 406. A food containing monochloroacetic acid must, in fact, be regarded as adulterated within the meaning of Section 402 (a) (2) regardless of the amount of the preservative present in the article.

"In making this decision we are not unmindful of the fact that competent investigators have determined that in the amounts necessary to exercise a preservative action in various beverages, monochloroacetic acid has not been demonstrated to exhibit a significant health hazard. Our interpretation of the statute is that a poison exhibiting toxicity of an order of magnitude comparable with such recognized poisons as bichloride of mercury, carbolic acid, and strychnine has no place in foods, regardless of the degree of dilution in which it exists in the articles consumed. The purpose of the Act is to safeguard consumers against the ingestion of any amount of avoidable poison with their foods.

"It is our conclusion, therefore, that monochloroacetic acid constitutes an adulterant in foods, no matter in what amount added, and that a food containing this substance is subject to seizure under the law and its shipper to criminal prosecution."

### MENTHOL NOT U.S.P.

The letter discusses the manner of listing, as an ingredient of drug products, menthol which does not meet the requirements of the *Pharmacopoeia*.

TC-378—December 29, 1941

"We have not indicated that the mere fact that menthol fails to meet the requirements of the *Pharmacopoeia* would serve as a bar to its use in non-official preparations.

"We are of the opinion that where mention is made of menthol on labels of products containing menthol which deviates from the requirements of the *Pharmacopoeia*,

the mention of this ingredient should be accompanied by a statement that it is not U.S.P. In addition, if the deviation is of a character substantially affecting the quality or properties of the finished article, the nature and extent of the deviation must be regarded as a material fact which should be stated on the label as provided by Section 201 (n) of the law."



### WHEAT GERM OIL—VITAMIN E

The letter discusses the labeling of wheat germ oil or products represented as having vitamin E activity.

TC-379—January 23, 1942

"There are at least two forms of vitamin E, alpha and beta tocopherol, which occur in natural products. There is evidence that these two compounds do not have identical vitamin E activity. We are not familiar with investigations which show the relative proportions of alpha and beta tocopherol which occur in wheat germ oil or if there is a fairly constant proportion of these compounds in wheat germ oil. If more precise information with respect to the presence of these compounds in wheat germ oil is not available, it would seem desirable to express the vitamin E content of this product in terms of its equivalent in vitamin E activity of alpha tocopherol. *'Nature,'* volume 148, page 472, October 18, 1941, carries an announcement of the adoption of 'dl-alpha-tocopherol acetate' as the International standard for vitamin E. Accordingly it is expected that an allotment of this standard will be sent to the Board of Trustees of the U. S. Pharmacopoeial Convention and this preparation, or a proto-

type standard, be made available for vitamin E determinations in this country.

"We can make no statement that would be applicable to all shipments of wheat germ oil as to whether or not the product would be subject to regulations under Section 403 (j). If it is apparent that the product is intended for human use as a source of vitamin E, it would undoubtedly be subject to the labeling requirements prescribed in these regulations. Since the need for vitamin E in human nutrition has not been established, obviously no minimum daily requirement can be prescribed. If wheat germ oil is recommended for human consumption as a source of vitamin E, consideration must be given to the fact that for a 200-gram rat the smallest quantity of wheat germ oil necessary to meet the rat's requirements is 25 mg. daily. In the labeling of any wheat germ oil offered for human use, consideration must be given to Section 201 (n) of the Food, Drug, and Cosmetic Act and the regulations thereunder."

---

### MALARIA PREPARATIONS

Although it would seem that true prophylaxis against malaria cannot be obtained through the use of cinchona alkaloids and that quinine merely controls the acute symptoms of malaria, the Administration will not proceed, pending completion of survey, against malaria preparations provided that they furnish at least 15 grains of quinine as an adult daily dose.

TC-380—January 23, 1942

"This Administration has not objected in the past to a therapeutic representation regarding malaria where the article furnished a sufficient quantity of cinchona alkaloid over an adequate period of time. Its position, adopted more than ten years ago, informed manufacturers that at least 15 grains should be administered daily over a period of eight weeks, without interruption. In view of the various papers that have been published during the past decade on the subject of malaria and the apparent change in the concept of the treatment of this disease, this Administration is now conducting an investigation to determine the consensus of present-day medical opinion regarding the various aspects of malarial therapeutics. Although it would

seem that true prophylaxis against malaria cannot be obtained through the use of cinchona alkaloids and that quinine does not cure nor eradicate malaria but merely controls its acute symptoms, this Administration will undertake no regulatory action against this class of preparation until its survey has been completed, provided, however, that these preparations furnish at least 15 grains of quinine as an adult daily dose.

"Upon the termination of this investigation, this Administration will express its opinion regarding the requirements of the various sections of the Federal Food, Drug, and Cosmetic Act as they pertain to preparations recommended for the treatment of malaria."



## SACCHARIN

Foods containing saccharin in any proportion are adulterated, and adulteration cannot be cured by any form of labeling. This does not apply to products for special dietary uses and sold pursuant to regulations under Section 403 (j).

TC-381—January 23, 1942

Wartime restrictions on sugar have prompted requests for permission to substitute saccharin for sugar in foods.

"\* \* \* Saccharin has no food value. It is several hundred times as sweet as sugar. The substitution of saccharin, even in minute amounts, for sugar, displaces relatively large amounts of sugar and materially reduces the food value of a food to which saccharin is added. Very shortly after the passage of the Food and Drugs Act of 1906, it was held that foods containing saccharin in any proportion would be regarded as adulterated under that statute

and that this adulteration could not be corrected by any form of labeling. We have continued to hold that position throughout the many years of enforcement of the 1906 Act and its successor, the Federal Food, Drug, and Cosmetic Act of 1938.

"\* \* \* of course, products which contain saccharin and are for special dietary uses may be legally manufactured and sold under the restrictions laid down by the regulations under Section 403 (j) of the Act. These regulations, which include the labeling requirements for special dietary foods, were published in the Federal Register of November 22, 1941."

## DIRECTIONS FOR USE

Full compliance with Section 502 (f) (1) requires that purchaser of medicine involved be informed not only how often and how much of the medicine is to be administered but also what it is for. If reference is made to the disease conditions for which the drug is not appropriate, it will become misbranded because of false representations concerning its therapeutic value.

TC-382—January 23, 1942

"In our correspondence we have objected to the proposed representations involving the treatment of certain disease conditions, because it is the medical consensus that the article would not be an adequate treatment therefor. As a result, you have deleted all specific therapeutic claims from the labeling but have provided directions for use which either must be construed as directions to take the medicine for the conditions previously referred to or else by implication that the medicine is a competent treatment for any disease. Under either circumstance, the directions are in fact inadequate.

"The dilemma with which you are faced is a result of attempting to provide ade-

quate directions for use, as required by Section 502 (f) (1) of the Food, Drug, and Cosmetic Act, for conditions for which the article is not appropriate. In our judgment, full compliance with this section of the law requires that the purchaser be informed not only how often and how much of the medicine is to be administered but also what the medicine is for. If you were to refer to the disease conditions previously mentioned, the medicine would then, in our judgment, become misbranded because of false representations concerning its therapeutic value. If the labeling were employed as it is now proposed, the directions for use would be inadequate."

## NOTICE TO MANUFACTURERS OF DIGITALIS PREPARATIONS

A substantial reduction in the potency of digitalis preparations will result in changing from U.S.P. XI to U.S.P. XII standards. During the transition period, conspicuous notice of the reduction in potency should be given on the labels.

TC-383—May 4, 1942

Examinations of a number of samples of each of the various pharmaceutical forms of digitalis indicate that a substantial reduction in potency will result in changing from

U.S.P. XI to U.S.P. XII standards. The exact reduction is not predictable but our data indicate that the reduction will amount to 40 per cent or more in at least one-half the cases.



In a drug in which standardization is as important as with digitalis, a change in potency of this magnitude is of the greatest interest to the physician and patient. It is suggested that during the transition period

in which U.S.P. XI and U.S.P. XII products may both be available, conspicuous notice of the reduction in potency be given on the labels.

### DIETARY SUPPLEMENT—NUX VOMICA

Where the label of a preparation consisting of a wine base containing vitamin B<sub>1</sub> and nux vomica extract would feature B<sub>1</sub> in a manner which would represent it as a dietary supplement, the article would be classified as a food and the presence of nux vomica would serve to adulterate it.

TC-384—May 29, 1942

Correspondent inquires as to legality under the Federal Food, Drug, and Cosmetic Act of a preparation consisting of a wine base containing vitamin B<sub>1</sub> and nux vomica extract.

"You have not furnished any labeling under which such a product is to be mar-

keted. We assume, however, that the label would feature vitamin B<sub>1</sub> in a manner which would represent it directly or indirectly as a dietary supplement. In such a case, it is our opinion that the article would be classified as a food, and the presence of nux vomica extract would serve to adulterate it."

### CHLOROBUTANOL

Chlorobutanol, when exempt from the requirements of Section 502 (d), should be declared as a chloroform derivative under Section 502 (e).

TC-385(Rescinds TC-357)—  
May 29, 1942

"\* \* \* we addressed you with reference to the declaration of chlorobutanol when used as a preservative and/or analgesic and stated that we were disposed to regard its declaration as required by Section 201 (n) of the Act rather than as a requirement of Section 502 (d) or (e).

"Since that time Regulation (d) under Section 502 (d) has been promulgated exempting the label of a drug containing chlorobutanol from bearing the statement 'Warning—May be habit forming' when the drug is for parenteral use only and contains

not more than 0.5 per cent of chlorobutanol as a preservative or not more than 3.0 per cent as an analgesic and preservative.

"We have recently had occasion to reconsider the question of the declaration of chlorobutanol on the labels of products entitled to this exemption. Section 502 (e) provides, among other things, that the label of a drug product shall bear, whether active or not, the name and quantity or proportion of any derivative of chloroform contained in the article. It is our understanding that chlorobutanol is in fact manufactured from chloroform and acetone. We are of the opinion that it should be declared under Section 502 (e)."

### ATHLETE'S FOOT—PHENOL AND CAMPHOR—CAUSTIC POISON ACT

A preparation for athlete's foot consisting of equal parts of phenol and camphor is too dangerous for indiscriminate use. Its label should contain the warnings required by Section 502 (f) (2).

Such a product is subject to the requirements of the Federal Caustic Poison Act.

TC-386—May 29, 1942

"We have your letter \* \* \* with regard to the sale of a mixture of phenol 50 per cent and camphor 50 per cent as a remedy

for athlete's foot. You ask whether this article may legally be sold over the counter.

"Our investigations indicate that such an article is capable of producing necrosis. It



is our opinion that it is too dangerous for indiscriminate use and that its sale should therefore be limited to prescriptions.

"To comply with the requirement of Section 502 (f) (2) of the Federal Food, Drug, and Cosmetic Act we are of the opinion that, when sold in interstate commerce, the label should bear warnings to the effect that the article should not be applied to damp skin or over extensive areas; should not be applied under a bandage; and

that if after use the skin turns white or is otherwise discolored, use of the preparation should be discontinued immediately unless the physician directs otherwise.

"Interstate shipments of the article are subject to the Federal Caustic Poison Act which, as you know, requires the appearance of the word 'Poison' on the label together with directions for treatment in case of accidental personal injury, and the name of the caustic substance."

### VITAMIN CAPSULES AND TABLETS

The letter discusses the declaration of ingredients in vitamin capsules or tablets.

TC-387—June 23, 1942

"As you know, Section 403(i)(2) calls for a complete listing of ingredients by their common names, except spices, flavorings, and colorings may be listed as such. Certainly a label for a vitamin capsule or tablet falling within the scope of Section 403 (j), bearing a list of all of the ingredients including excipients, fillers, binders, or other fabricating ingredients, cannot be adversely criticized from the standpoint of the requirements of Section 403(i)(2). We recognize, however, that in many instances the exact nature of the excipients and fillers may not be of any particular interest to the user.

"In the absence of any definite information that the purchaser is being denied essential information to which the Act entitles him, we will not for the present take exception to the declaration of the small quantities of excipients and fillers which do not possess any particular dietary significance by some general heading such as 'Excipients and Fillers.' If flavoring and coloring are also employed, they may be declared as flavors and colors. If they are artificial, this fact should be revealed. Should it develop that the consumer is being denied information of value, or that such a method of ingredient declaration is used to conceal information of importance, we will of course modify our present position.

### SACCHARIN TABLETS

The letter discusses the labeling of saccharin tablets.

TC-388—July 27, 1942

"We have your letter which discusses paragraph 125.07 of the regulations for products for special dietary uses and inquiring if this requirement applies to the ordinary ½ or 1-grain saccharin tablets.

Since saccharin is recognized in the *United States Pharmacopoeia* as a drug, we have been disposed to class saccharin in tablet form as a drug and therefore subject to the drug labeling requirements of the

Food, Drug, and Cosmetic Act rather than to the regulations under Section 403(j) pertaining to those special dietary foods which contain saccharin as an ingredient. If, however, saccharin tablets are sold under representations which in any way imply that they may be used by the ultimate consumer in the home as a sweetening agent, we feel that Section 201(n) of the Act can be invoked to insist that the labels of such saccharin tablets reveal the material fact that the article has no food value whatever."



## CLASSIFICATION OF DRUGS UNDER SECTION 502(j)

The Administration has classified drugs in three groups under Section 502(j): (1) those which are safe for indiscriminate use, (2) those which are safe only when administered under the supervision of a physician, and (3) those whose toxic potentialities are such that they should not be used even under a physician's supervision.

TC-389—August 6, 1942

"Replying to your inquiry, Section 502(j) of the Federal Food, Drug, and Cosmetic Act defines as misbranded drugs which are dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof. In considering the application of this section of the Act to the drugs which we encounter in interstate commerce, it is our opinion that drugs fall into three classes: (1) those which are safe for indiscriminate use, (2) those which are safe only when administered under the supervision of a physician, and (3) those whose toxic potentialities are such that they should not be used even under a physician's supervision. In this latter group fall such drugs as dinitrophenol, dinitrocresol, and their derivatives, diethylene glycol, ethylene glycol, carbitol, Cellosolve, and all other glycols except glycerin and propylene glycol if present in drug products in appreciable quantities.

"The philosophy behind our position with respect to this class of drugs is that their therapeutic usefulness is either totally lack-

ing or so minor in comparison to the great harm which they are capable of causing that informed physicians would under no circumstances employ these drugs. In our opinion, no form of labeling can be devised for these articles which will remove this danger. Hence, any sale or the proffer for sale of these drugs under any labeling which offers them for drug use automatically misbrands them.

"Some of the glycols appear to be reasonably safe even for use in articles appropriate for self-medication, propylene glycol in particular. Others may perhaps be safe in preparations intended for specific purposes or for use under particular conditions which would not involve danger to the user. The method of use of the preparation, the identity and proportion of the glycol, and other details would have to be taken into consideration in each particular instance. Finally, it is to be pointed out that it is the responsibility of the manufacturer to determine beyond doubt that any article sold by him for drug use is safe for such use when taken according to the directions prescribed on the labeling."

## SCABIES

Preparations for the treatment of scabies should be distributed only by physicians or on prescription.

TC-390—August 17, 1942

"We have recently had occasion to give consideration to the safety of articles sold directly to the lay public and represented for scabies. We interrogated a majority of the leading dermatologists of this country and found them in overwhelming agreement that the layman is incapable of diagnosing scabies; that even if diagnosis of the condition is made and the article to be used is capable of killing the *Acarus*, the layman cannot treat himself safely and effectively for this condition; and, finally, that the hazard of a dermatitis resulting from the treatment of this condition is of sufficient significance to cause self-medication to be an unsafe procedure. The preponderance of information concerning the dangers of the treatment of scabies by the lay public per-

tains to the use of the usual sulfur mixtures. The medical literature on the use of benzyl benzoate preparations reveals that this medication also is capable of causing a dermatitis in a significant number of users, and, therefore, these products fall into the same category as sulfur preparations.

"In view of the above considerations, this Administration has altered its viewpoint concerning the propriety of the indiscriminate distribution of preparations offered for the treatment of scabies. We are, therefore, notifying manufacturers of such products of our change in viewpoint. It is our opinion that your product may not comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act, and we suggest that the labeling of the preparation be revised in order to limit its distribution to by or on the prescription of a physician."



DIGITALIS

The sale of digitalis need not be limited to prescriptions if the label bears notice to purchasers to observe their physicians' directions.

If labeling bears any reference to an unofficial method of assay, and such a reference proves misleading, the product will be misbranded.

TC-391—August 21, 1942

Comment on proposed labeling for Digitalis Tablets.

"Our consideration of the conditions under which digitalis is prescribed and used leads us to the conclusion that it is not necessary that sales of it under ordinary circumstances be limited to prescription use. It is our understanding that people do not undertake to medicate themselves with digitalis. On the other hand, a physician, having ascertained the digitalis requirement of a particular patient, will probably instruct him to continue the use of the drug on a specified dosage schedule for a considerable period of time. Under the circumstances, it would appear desirable to have the drug labeled in such a way that its sale without

a prescription will not be illegal. This, we think, could be accomplished by the substitution for the so-called 'prescription only' legend of some such phrase as 'Notice to purchaser: Use this drug in strict accordance with your physician's directions.'

"We are not at all sure that any reference on the label to an assay in addition to the official assay will not prove confusing. As we understand it, the human assay of this product does not indicate a potency any different from that obtained by the official method. If the labeling bears any reference to an unofficial method of assay and such a reference proves 'misleading in any particular' to the purchaser, it will constitute misbranding under Section 502(a) of the Federal Food, Drug, and Cosmetic Act."

NOTICE TO MANUFACTURERS OF PREPARATIONS OF CINCHONA ALKALOIDS FOR THE TREATMENT OF MALARIA

The letter discusses the use of cinchona and cinchona alkaloids in malaria and the minimum daily amounts necessary.

TC-392—August 20, 1942

As a guide to its activities under the provisions of the Federal Food, Drug, and Cosmetic Act in the consideration of preparations offered for the treatment of malaria, the Food and Drug Administration requested an expression of opinion from the National Research Council as to the use of the cinchona alkaloids in this field. The request was referred by the Council to its Division of Medical Sciences, Subcommittee on Tropical Diseases. We are now in receipt of a report from the National Research Council in which it states that a preparation of one or more of the crystallizable cinchona alkaloids (quinine, quinidine, cinchonine, cinchonidine) for the treatment of malaria should provide daily for 7 consecutive days, for adults, at least 20 grains of the alkaloid or alkaloids.

The minimum amounts of these alkaloids which should be provided daily for the same period for children are as follows:

Age	Grain
Under 1 year	2½
1 to 2 years	5
3 to 4 years	7½
5 to 6 years	10
7 to 8 years	12½
9 to 10 years	15
11 to 12 years	17½
13 years and over	20

It is the understanding of this Administration that the reference to "Cinchona Alkaloids" includes the commonly used salts of these alkaloids.

The Council states that in making this recommendation it recognized that 20 grains of the cinchona alkaloids a day do not provide the optimum dose for adults—which should be 30 grains—but that the minimum of 20 grains is specified as a compromise to provide for an effective dose and to conserve the stocks of these alkaloids during the war period.



The Council has expressed the opinion also that the cinchona alkaloids are not effective in the prophylaxis of malaria.

In its enforcement program the Food and Drug Administration will be guided by this authoritative expression of opinion and will regard as misbranded preparations of cinchona alkaloids offered for the treatment of malaria which, when consumed in accordance with the directions in their labelings, provide less than the dosages specified above.

The Administration heretofore has expressed the opinion—and takes this occasion to emphasize it—that directions for use, to be adequate, should include instructions to repeat the treatment if a relapse occurs.

It has been noted that cinchona alkaloids and preparations of them are sometimes marketed in packages which do not contain amounts of the active principles sufficient to constitute a complete treatment in accordance with the above-mentioned schedule. Consideration should be given to the possibility of deception, in violation of the Federal Food, Drug, and Cosmetic Act, result-

ing from the sale of a package labeled to indicate that it contains a treatment for malaria, if the amount of medication supplied in the package is insufficient for that purpose.

Some preparations of the cinchona alkaloids offered as malaria medicines contain active amounts of cathartic drugs. There appears to be no rational basis for such a combination. Some patients suffering with malaria may not need a cathartic. Those who may need such additional medication should base the dosage upon the need for it; in other words, the amount of the cathartic administered should not depend upon the need for the cinchona alkaloids. There is no objection to advising purchasers to use some suitable cathartic drug in connection with the malaria treatment if constipation occurs.

This notice supersedes the press release of January 3, 1939, entitled "Malaria Preparations Must Comply With Food and Drugs Act Say Federal Officials," issued by the Office of Information, United States Department of Agriculture.

---

## NOTICE TO MANUFACTURERS OF VETERINARY ANTHELMINTICS

The letter suggests a warning to be placed on the labels of veterinary anthelmintics due to the potential toxicity of all known effective worm remedies.

TC-393—August 21, 1942

The Food and Drug Administration has received over a period of years numerous complaints of deaths of animals, particularly dogs, allegedly due to the administration of anthelmintics.

Anthelmintics, in order to be effective, must be given in doses which cannot be considered free from harm. In some cases they may actually be the primary cause of the death of the animals to which they are administered. More frequently perhaps they aggravate the disease condition already existing, thereby hastening death.

It is a matter of common knowledge that owners of animals, especially owners of pets, have within recent years become "worm-conscious" and have sometimes reached the erroneous conclusion that most ailments of pets as well as other animals are associated with or directly due to worm infestation. This has led to the extensive use of anthelmintics where they were not indicated.

This Administration has had extensive correspondence with manufacturers of anthelmintics in which it has pointed out that effective doses of anthelmintics cannot be administered safely to animals under all conditions. The Federal Food, Drug, and Cosmetic Act requires that drugs be labeled with adequate directions for use and adequate warnings against misuse. It defines as misbranded drugs which are dangerous to health when used in accordance with the directions provided in the labeling. To avoid conflict with the requirements of the Act these provisions should be given careful consideration. Some such information as the following, conspicuously displayed in connection with the directions for use of anthelmintics, would be in the user's interest and would contribute toward compliance with the requirements of the law:

"Warning: All known effective anthelmintics (worm remedies) are more or less toxic to animals. This preparation should not be administered to sick, feverish, physically weak, or undernourished animals unless on the advice of a veterinarian."

---



## SCABIES

The administrative program to enforce the policy announced in TC-390 with respect to preparations for the treatment of scabies is postponed because of the war situation.

TC-394—November 30, 1942

(The letter quoted below is typical of those addressed to manufacturers of preparations offered as treatments for scabies, who had previously been advised of the Administration's opinion that such products should be distributed only by physicians or on prescription).

"In this correspondence we had questioned the legality of your preparation from the standpoint of the requirements of the Federal Food, Drug, and Cosmetic Act. Our letters had advised you of our purpose to notify manufacturers of products of this type of our view that their distribution was in violation of the Food, Drug, and Cosmetic Act and that it was our purpose to follow with regulatory action in those cases where manufacturers despite this notice continued distributing the products.

"Our program on this particular project has necessarily been changed since the out-

break of hostilities due to the loss to the military forces of a proportion of our trained personnel and the diversion of the remainder of the force to special wartime tasks. We have been obliged to forego, from sheer necessity, the attention which we had planned to give to many products subject to the Food, Drug, and Cosmetic Act which were of relatively minor importance compared with other matters now engaging our attention. It is impossible to make an appropriate follow-up at this time on the sulfur remedies offered for the treatment of scabies. You are entitled, in all fairness, to know of this change in our program. I am taking this occasion to advise you that until further notice no action will be directed against your product by reason of the claims made in its labeling for the treatment of scabies, nor against similar products distributed by other manufacturers."

## SALAD DRESSING—MINERAL OIL

The regulations under Section 403 (j) may not be used as a subterfuge to distribute salad dressings containing mineral oil for general food use as distinguished from special dietary use.

TC-395—December 18, 1942

Correspondent requests comment on a proposed label for a so-called mineral oil salad dressing. The proposed label reads:

"\* \* \* Brand Contents 1 Gallon

"Mineral Oil Dressing

"A special dietary preparation less fattening than mayonnaise. Its low food value makes it useful in the diet of persons inclined toward obesity. Made with 80% by weight, non nutritive white mineral oil U.S.P. Distilled Vinegar, eggs, sugar, salt & spices. Contains no cereal starch. \* \* \*"

"While this label is for a gallon container, we are advised that you propose similar labeling for pint and quart size containers with the appropriate volume declaration.

"It is our understanding that this proposed product is intended for distribution to restaurants and hotels. \* \* \*

"It is apparent from the label statements that you have undertaken to place the product in the category of a food for special

dietary uses subject to the special labeling regulations set up under Section 403 (j) of the Food, Drug, and Cosmetic Act. These regulations permit the use of mineral oil in certain foods for special dietary uses under labeling of the kind you have adopted. However, we have always held that under the general provisions of the law, mineral oil, because of the lack of any food value, may not be used in foods for general distribution and that such foods when so distributed are adulterated under any form of labeling because of the substitution of a non-food ingredient for the food oil normally expected in such food products. We cannot escape the conclusion that your product, packed and distributed as indicated above, is not intended for special dietary use but is for distribution to the general public through restaurant and hotel use. Under the circumstances, we must regard your product as adulterated by reason of the use of mineral oil in place of an edible food oil."



## NOTICE TO MANUFACTURERS OF LIVESTOCK AND POULTRY REMEDIES

Administration issues a notice to manufacturers of livestock and poultry remedies with respect to the requirements of the Act.

TC-396—December 21, 1942

Investigations made by the Food and Drug Administration show that there are many livestock and poultry remedies on the market with labelings that do not conform with provisions of the Federal Food, Drug, and Cosmetic Act. The labelings bear indefinite directions for use and contain no information about the purposes for which the preparations are to be used and no adequate warnings for use. Some of these preparations were found also to bear on the labels long lists of ingredients, of which many are not active drugs or are not present in therapeutically significant amounts.

The Food, Drug, and Cosmetic Act defines such products as misbranded unless their labelings bear adequate directions for use, adequate warnings, and the common name of each active ingredient, together with the quantity or proportion of certain specifically mentioned drugs.

Directions for the use of a drug, to be adequate as required by the Act, should furnish not only information as to the dosage, frequency, and duration of administration of the drug, but also information concerning the purpose for which the drug is to be used. For example, a product consisting of therapeutically active amounts of expectorant drugs, when used as directed, may be properly labeled as an expectorant to aid in loosening the accumulation of mucus in the throat. For such purposes the directions may be adequate for its

use when recommended to be used three or four times a day for a period of two or three days and not for an indefinite, prolonged period of time. As another example, a product consisting of therapeutically active amounts of astringent drugs may be properly labeled as an astringent for simple diarrhea when directed to be used three or four times a day for two or three days, with a warning to the effect that astringent drugs are harmful if administered over a prolonged period of time.

Many other veterinary preparations investigated were found to consist of ingredients having entirely dissimilar physiological actions. Such preparations are regarded by informed veterinarians as irrational, and adequate directions for their use cannot, in our opinion, be prepared.

In determining whether or not the ingredients of a preparation can be properly declared active, as provided in the act, the manufacturer should determine the exact amount of each ingredient present in each dose recommended for each species of animal. If it is concluded from this information that the product, when used as directed, furnishes an amount of any ingredient which would have no physiological effect, it should not be declared directly or indirectly as an active ingredient. While there would be no objection to declaring both the active and inert ingredients, they should be conspicuously designated as such under appropriate headings.

---

## VENEREAL DISEASE—CHEMICAL PROPHYLACTICS

No action is contemplated at present against a one-tube chemical venereal disease prophylactic which contains four or more grams of an ointment consisting of 30 to 33 per cent calomel, plus some other bactericidal substance, and bears adequate (and these are suggested) directions for use.

TC-397 (Supplements TC-355)—  
January 7, 1943

"At that time we informed you that it was our position that an article which claimed to protect against venereal disease should consist of two tubes. One tube should contain an ointment consisting of 30 per cent to 33 per cent of calomel and possibly some added antiseptic; the other tube should consist of a silver preparation. We have not had occasion to change our

point of view which, as we informed you originally, is in conformity with that of the leading authorities in this field, but as a result of the issuance of citations such as you have received many manufacturers made representations to us which apparently went to show that their 'one-tube' article was an efficient prophylactic. Pending the acquisition of further facts it does not appear practicable from a legal standpoint to proceed against manufacturers solely by



reason of the lack of the extra tube containing a silver salt. Consequently, for the present we shall defer action against one-tube chemical venereal disease prophylactics which contain four or more grams of an ointment consisting of 30 to 33 per cent calomel, plus some other bactericidal substance, and which have adequate directions for use. By adequate directions for use we mean statements to the effect that—

1. The article should be used within two hours. After this time the likelihood of protection becomes less and less.

2. The individual should urinate.

3. He should thoroughly wash the penis and adjacent parts with soap and water and then dry.

4. He should insert the tip of the tube into the urethra (opening of the penis) and inject about one-third of the contents of the tube into the canal, distributing the ointment along the canal by means of external massage and holding it within the canal for five minutes.

5. He should then squeeze the remainder of the contents of the tube onto the surface of the penis and adjacent anatomical parts, the ointment to be well rubbed in by means of massage.

6. The penis should then be wrapped in a container which is to accompany the prophylactic and is not to be washed for at least two hours."

### ABSORBENT COTTON

Unsterile cotton in five-pound rolls may be marketed under definite labeling conditions which preclude confusion with sterile USP product.

TC-398—January 21, 1943

Correspondent has inquired with reference to the distribution of absorbent cotton in five-pound rolls.

"While the *Pharmacopoeia* does not so state, we assume that the limitation in that text on the size of the package was for the purpose of facilitating sterilization of the article and in the interest of the maintenance of the sterile condition. We are not disposed, therefore, to consider favorably any proposal for deviation from the official packaging requirements for cotton purporting to be the *Pharmacopoeial* product.

"There may be a legitimate demand for absorbent cotton in which sterility is of no importance. We are of the opinion that no purpose would be served by restricting the size of a package of cotton of this type to not more than one pound. We are not disposed, therefore, to take exception to the marketing of nonsterile absorbent cotton in five-pound rolls under conditions which will assure against its use for purposes in which sterility is of importance.

"Such conditions would include:

"1. The conspicuous announcement on the

package that the cotton is not sterile. Such a declaration would preferably be made directly in connection with the name of the product wherever it appears upon the package and in type of a size and style which will make the declaration appear at least as prominently as any other statement on the label.

"2. A conspicuous statement on the label to the effect that the cotton should not be used on cuts or sores, or in other conditions where the skin is broken or where a sterile cotton is needed.

"3. A showing on the label that the article differs from absorbent cotton defined in the *United States Pharmacopoeia* in that it is not sterile. If it differs in any other respects from the *Pharmacopoeial* specifications specific information as to the nature and extent of the deviation should of course appear upon the label.

"4. Avoidance of brand names or descriptive phraseology such as 'first grade,' 'high quality,' 'superior brand.' In order to avoid confusion brand names used for sterilized cotton should not be used also on an unsterile cotton."



**MALARIA—TOTAQUINE**

The letter discusses the labeling of totaquine and the required dosages in the treatment of malaria.

TC-399—January 21, 1943

Correspondent inquired regarding the labeling requirements for totaquine offered for the treatment of malaria.

"The National Research Council has recommended that the dosage of totaquine for adults be ten grains three times a day for seven days.

"There appears to be no well-defined medical concensus as to the quantity of totaquine necessary for the adequate treatment of malaria in children. For the present we will not adversely criticize the same schedule for children as has been recommended by the National Research Council for quinine, as set forth in our trade notice issued on August 20, 1942." (TC-392) "If it appears that some other

dosage schedule would constitute a more suitable treatment for malaria in children, the labeling for totaquine preparations should, of course, be correspondingly revised. If such a change is to be made in the dosage schedule for children, I will correspond with you at that time. The recommended dosage for both adults and children should be continued for seven consecutive days, and the labeling of the preparation should bear instructions to repeat the treatment if a relapse occurs.

"For obvious reasons, the Administration is of the opinion that it is appropriate for a single container of a totaquine preparation for the treatment of malaria to contain not less than 210 grains of this ingredient in order that it will provide a complete seven-day treatment."

**SULFATHIAZOLE—SULFANILAMIDE**

Sulfathiazole-impregnated finger bandages have been considered, in particular cases, to be safe for indiscriminate sale.

Sulfonamide ointments intended for distribution to the general public would be considered "new drugs."

Some sulfathiazole-containing nose drops have been considered safe for indiscriminate use, but they are still considered "new drugs."

TC-400—April 7, 1943

"We have your letter \* \* \* asking whether a sterilized sulfathiazole-impregnated Handi-Tape or Band-Aid type of product is a new drug, and whether a five per cent sulfathiazole ointment or cream may be labeled for over-the-counter sale to the laity.

"As you are aware, in notices issued to the trade and in correspondence, this Administration has expressed the opinion that the sulfonamide drugs are too dangerous for indiscriminate self-medication and that their distribution should be limited to use by or on the prescription of physicians or dentists; but that these drugs, when intended for veterinary use only, if adequately labeled, need not be restricted to professional use.

"Recently, consideration has been given to new drug applications submitted under the requirements of the Federal Food, Drug, and Cosmetic Act for small adhesive gauze bandages (Band-Aid type) impregnated with sulfathiazole. On the basis of the evidence of safety provided in the particular cases, we concluded that this type

of article was safe for use without medical supervision when used under the conditions and following the directions proposed in the labeling.

"Sulfonamide ointments intended for distribution to the general public for self use would be considered as new drugs as that term is defined under Section 201 (p) of the Act."

"We have your letter \* \* \* with reference to the over-the-counter sale of nose drops containing sulfathiazole.

"Recently, consideration has been given to applications submitted under the requirement of the Federal Food, Drug, and Cosmetic Act relating to new drugs and to the data furnished with reference to the safety of preparations of the type referred to in your letter, and offered for distribution to the general public for self-use. Certain of these applications have been permitted to become effective. Our decision in this regard has been based on submitted evidence of safety for use of the particular product under the conditions proposed in the labeling. Such products are still considered new drugs."



### PARA-AMINOBENZOIC ACID

There is no convincing evidence that para-aminobenzoic acid is a food essential or will cause restoration of the pigment of gray hair. It may interfere with the effects of the sulfa drugs.

TC-401—April 19, 1943

"Published reports of investigations with experimental animals relating to the possible nutritive value of para-aminobenzoic acid do not lead to the conclusion that this compound is a food essential of man or other animals. We are reliably informed that competent investigators have been unable to confirm the observation that para-aminobenzoic acid administration will cause

restoration of the pigment of gray hair in man.

"Certain experiments seem to indicate quite strongly that para-aminobenzoic acid has an inhibiting effect on the action of the sulfa drugs. To add the amount of para-aminobenzoic acid which you contemplate to a vitamin preparation intended for indiscriminate use by the public is in our opinion unwarranted."

### GLYCOLS IN COSMETICS

The letter discusses the use of glycols in cosmetic preparations to be applied to the unbroken skin.

TC-402—May 14, 1943

Correspondent inquires regarding the use of glycols in cosmetic preparations to be applied to the unbroken skin and if there is any objection to the use of any of the glycols in such preparations.

"The Federal Food, Drug, and Cosmetic Act, as you know, provides that a cosmetic shall be deemed to be adulterated if it contains any material which may be injurious to users. Propylene glycol and glycerin are generally accepted as safe ingredients.

"While other glycols may possibly be safe for use in small quantities in preparations intended for external application, it is

known that certain ingredients, such as wetting agents, may increase the amount of absorption and consequently the toxicity of these glycols. For this reason, we feel that in the light of our present knowledge any amount of such glycols as ethylene glycol, carbitol, and diethylene glycol, in excess of five per cent in a preparation for topical application to small areas of the body would constitute a hazard.

"In the case of such preparations as sun-screen lotions and protective creams, where the material is applied to extensive areas of the body, we feel that the above glycols may constitute a hazard in any concentration."

### OILS IN CANNED TUNA FISH

The letter discusses the oils used as packing medium of canned tuna fish and the label statement during emergency.

TC-403—June 7, 1943

"We have your letter \* \* \* stating that your label manufacturer \* \* \* has obtained an interpretation from us to the effect that the wording 'Packed in Vegetable Oil' may be used on labels of canned tuna fish in lieu of a specific statement naming the oil which is used. You inquire whether this is correct.

"A number of packers have advised us that they anticipate being unable to obtain constant supplies of cottonseed oil during the coming packing season and have requested our comments on various methods of labeling the product packed this season. Our replies were essentially as follows:

"(1) Labels reading 'Packed in Cottonseed Oil' should not be used on a product which is packed in another oil.

"(2) If constant supplies of a single oil or blend of oils is expected to be available, the label should read, for instance, 'Packed in Corn Oil' or 'Packed in Corn and Soybean Oils.'

"(3) If it is anticipated that the supplies of oils will vary during the season, no objection will be taken during this emergency period to the temporary use of such a designation as 'Packed in Cottonseed and/or Corn and/or Soybean Oils' or 'Packed in



Salad Oil (Cottonseed and/or Corn and/or Soybean).'

"(4) If the emergency facing any one packer is such that he cannot predict whether he can limit his pack to one or more of three oils we would not for the period of his emergency, take exception to

the broader term 'Vegetable Oil.'

"We doubt, however, that cases will arise where none of the oils named on a label will be available, hence we do not anticipate at this time that there will be any need to resort to the statement under (4) above."

### MINERAL OIL

Mineral oil, if used in foods for general distribution, would violate the Act.

TC-404—July 13, 1943

"You submitted \* \* \* proposed labeling for Heavy Mineral Oil U.S.P. for use both as a medicinal agent and for employment for general culinary purposes in various types of foods.

"U.S.P. mineral oil has a legitimate medicinal use. The directions you propose for use of the article as a drug conform with the general requirements for drug labeling set up by the Food, Drug, and Cosmetic Act.

"Mineral oil, as you recognize, is utterly without nutritional value. This Administration, in applying the terms of the Food, Drug, and Cosmetic Act as well as its predecessor the Food and Drugs Act, has consistently held that a product having the properties of mineral oil can only be regarded as an adulterant in foods. Action has been repeatedly taken under the terms of the law by seizure and by criminal prosecution in the case of products such as salad dressings in which mineral oil has been substituted wholly or in part for a food oil.

"It is quite true that in the formulation of regulations under Section 403 (j) of the Food, Drug, and Cosmetic Act, the Agency has recognized in its findings of fact that the value of a food for special dietary use may depend on the presence therein of a constituent which is not utilized in normal metabolism and which consequently has no nutritive value. It cited mineral oil as an example of an ingredient which may be used for the reduction of caloric intake in a food for special dietary uses. The regulations set up under Section 403 (j), however, call for a special form of labeling which clearly and unequivocally sets the product apart from foods for ordinary and general nutritional uses.

"It has become increasingly apparent that under the stress of current food fat shortages, some manufacturers and distributors have turned to mineral oil as a sub-

stitute for the food fats in a wide variety of food products normally prepared from animal and vegetable fats and oils. Under the guise of the special labeling prescribed by regulation under Section 403 (j), efforts are being made to distribute these debased products to a large segment of the population having no special dietary requirement for diminished caloric intake. In many instances, such as sale to restaurants, even the protection intended to be afforded by the labeling prescribed by Section 403 (j) is denied the ultimate consumer. The intent of the regulation covering foods for special dietary uses was clearly to insure that the peculiar properties of the product would be made known to the individual consumer and that consumption would be limited to those who must restrict their caloric intake.

"The directions which you propose to employ for the article as a drug warn that in the treatment of occasional constipation the article should not be used directly before or after meals. Investigations on animals have shown that the ingestion of mineral oil prevents proper assimilation of several of the essential vitamins and minerals. These studies show that the interference with assimilation is greater when the oil is intimately mixed with food as, for example, in the form of salad dressing. It is quite probable that the assimilation of fat is also interfered with to some extent. Furthermore, there is a rather strong probability that other evidence will be forthcoming which will establish that mineral oil used as a food or incorporated in a food is deleterious to health. It is entirely conceivable that such evidence will be sufficiently persuasive to justify a reconsideration of the present position which permits its employment in foods intended for special dietary uses, and to prohibit its sale except as a drug.

"It is evident that your proposed label is designed to promote the use of mineral oil



for a variety of culinary purposes. The suggestion that it is to be used for general household culinary purposes is completely incompatible with the correctly phrased warning that when used for medicinal purposes it should not be taken directly before

or after meals. It is our considered judgment that the proposed labeling or any form of label which advocates food uses of mineral oil would be seriously misleading and therefore contrary to the provisions of the Food, Drug, and Cosmetic Act."

### SAUERKRAUT WITH VINEGAR

The Administration is presently not disposed to object to the addition of vinegar to sauerkraut to prevent impairment of quality. Such an article should be labeled "Sauerkraut with Distilled Vinegar Added," to be followed by the ingredient statement.

TC-405—July 16, 1943

Comment to firm regarding the interstate shipment of a consignment of unprocessed glass-pack sauerkraut which contained vinegar as a part of the liquid packing medium.

"It has been consistently held for years that vinegar is not a normal ingredient in sauerkraut, and in our judgment there is no necessity for adding this substance to canned sauerkraut which has been processed by heat. It is possible that, in the present emergency when containers are not available which will permit the normal heat processing, certain modifications in technique are necessary in order to get the product to the housewife in a sound and edible condition. While we are conducting some experiments upon the influence of different fills on the keeping quality of [unprocessed] kraut in glass containers we have made no

studies on the necessity for the addition of vinegar during present emergency conditions. Certainly it is to be preferred to the use of chemicals such as sulfites and benzoates.

For the time being, and without prejudice to a different opinion in the light of more complete information, we are not disposed to object to the addition of distilled or other vinegar in amount necessary to prevent impairment of quality while in the channels of commerce. It is, of course, understood that the kraut is a fully fermented product, containing after repacking at least one per cent of lactic acid, derived from such fermentation.

We believe that such an article should be labeled "Sauerkraut with Distilled Vinegar Added," this name to be followed by the ingredient statement."

### PRESERVING POWDERS

Preserving powders are not safe for home canning.

TC-406—July 22, 1943

"I have your request for an opinion regarding the use of chemical preservatives by home canners. You quote a paragraph from Farmers' Bulletin 1762, 'Home Canning of Fruits, Vegetables and Meats,' which reads as follows:

'The use of chemical preservatives, such as salicylic acid, sodium benzoate, and "canning powders," should be avoided in home canning any kind of food. These chemicals vary in their effects on the human body, some being more harmful than others. Therefore, the safe way for the home canner is to process foods adequately with heat and not to use chemical preservatives.'

"I am fully in agreement with the advice

given in this paragraph. Practically all the substances proposed in the past as chemical preservatives have limited value as such and in view of the known harmful effects of some of them and the doubtful safety of others, they should not be used as substitutes for more efficacious and safer processes of sterilization by heat.

"You cite salicylic acid, sodium benzoate and 'canning powders' as typical chemical preservatives. The term 'canning powders' includes boric acid and its compounds, and substances like potassium metabisulfite which yield sulfur dioxide when brought in contact with an acid-reacting food product. Salicylic acid and boric acid and its compounds are toxic. Their use for home canning constitutes a definite health hazard.



Sulfites and sulfur dioxide have the property of rapidly and completely destroying vitamin B<sub>1</sub>. For this reason alone, the use of sulfites in home-canned foods should be avoided because vitamin B<sub>1</sub> is essential for man and its absence from the diet causes the disease beriberi. The importance of maintaining the vitamin content of the diet has been recognized by governmental agencies which have sponsored the enrichment of bread and flour in accordance with the recommendation of the National Research Council. Such enrichment includes the addition of vitamin B<sub>1</sub>. Certainly the enrichment program will be materially offset if preserving powders which destroy vitamin B<sub>1</sub> are employed in home canning.

"It is true, of course, that sulfur dioxide is now employed in a limited number of products, notably in dried fruits to prevent darkening rather than as a general preservative. With this limited usage the probability of heavy individual consumption of sulfur dioxide in the diet is slight. With general employment by home canners of this preservative it is not only possible but probable that entire households, including the young and the old, the weak and the strong, the sick and the well, would consume sufficient quantities of the preservative to create chronic or cumulative effects and serious vitamin B<sub>1</sub> deficiencies.

"Chemical preservatives not only present a health hazard when used by the home

canner but they are far from satisfactory substitutes for heat treatment. All the chemical preservatives named, including benzoate of soda, are of doubtful efficacy under all conditions which may be encountered. They are restricted in their usefulness in that they prevent or retard the growth of certain groups of microorganisms but are useless against others. They are not noted for their germ killing properties but ordinarily only retard or prevent microbial development. In most instances they act effectively only in acid mediums. Experiments have shown that some of them at least will not prevent the production of the deadly toxin or poison of the food poisoning germ *Clostridium botulinum*.

"The last named fact is of particular importance since experience has shown that the household use of chemical preservatives not infrequently leads to carelessness and neglect of the usual sanitary precautions and to attempts to utilize unfit raw material. There is every probability that the home canner who is encouraged to use chemical preservatives will place undue confidence in their effectiveness. Fatalities from improperly prepared home-canned foods occur entirely too frequently.

"We do not believe that the present war emergency offers any valid reason for condoning the use of chemical preservatives by home canners in lieu of tested and approved processes of heat sterilization."

---

### VITAMIN B<sub>1</sub> TABLETS FOR USE IN ENRICHING BREAD

A label declaration that vitamin B<sub>1</sub> tablets intended for use in enriching bread contained 150 milligrams of vitamin B<sub>1</sub> would be misleading unless the product actually furnished that amount of the pure substance.

TC-407—August 5, 1943

"We refer to \* \* \* the labeling of thiamine hydrochloride tablets intended to be used in the enrichment of bread.

"The question has been raised as to whether a declaration of 150 milligrams of thiamine hydrochloride per tablet would be interpreted to mean that the product contained 150 milligrams of chemically pure, moisture-free thiamine hydrochloride or 150 milligrams of thiamine hydrochloride of U.

S.P. purity.

"Since the article is to be used by bakers who must use the vitamin B<sub>1</sub> declaration in calculating the amount to use in fortifying bread, we cannot escape the conclusion that the baker would expect the article to furnish 150 milligrams of pure thiamine hydrochloride. A declaration that the tablet contained 150 milligrams of vitamin B<sub>1</sub> in our opinion would be misleading, unless the product actually furnished that amount of the pure substance."

---



### PYRIDOXINE AND PANTOTHENIC ACID IN YEAST TABLETS

Under the circumstances, the Administration cannot be assured that the declaration of pyridoxine and pantothenic acid tablets will not mislead, even though the declared quantities of vitamins are correct and the label states that the need for these vitamins in human nutrition has not been established.

TC-408—September 9, 1943

The correspondent submits text of a proposed label for brewers' yeast tablets.

"The label bears the statement 'contains all the water-soluble B-complex vitamins as found in this natural source,' followed by 'Used as a supplement in the treatment of B-complex deficiencies.' The product, if taken in accordance with the directions for use, namely, eight tablets daily, will provide according to the declarations on the label, about 0.35 milligram of pantothenic acid and 0.064 milligrams of pyridoxine. You have properly qualified this declaration by a statement showing that the need for these two vitamin factors in human nutrition has not been established. However, there have

been reports that permit some sound conclusions with respect to the quantities of these two substances which are normally present in the human body. Other reports with respect to animal requirements support the position that the quantities of pantothenic acid and pyridoxine supplied by this product may not be consequential.

Under these circumstances we cannot be assured that the declaration of these vitamins will not mislead even though the declared quantities of vitamins are correct and the label bears the statement that the need for these vitamins in human nutrition has not been established. This comment likewise may be applicable to factors of the B-complex other than those specifically named."

### GOODS SHIPPED FOR PROCESSING, LABELING, OR REPACKING

The letter discusses a form of agreement for merchandise shipped in bulk.

TC-409—September 18, 1943

"In our opinion the sample agreement submitted would not suffice to relieve you of the responsibility for completely labeling merchandise shipped pursuant thereto. The primary objection to the 'agreement' is that the attached label \* \* \* in our opinion would misbrand the article.

"The last paragraph of the proposed

agreement seeks to shift to the repacker the responsibility for the legality of the label. We do not think that this meets the requirements of either the statute or the regulations.

"Of course there is no requirement that the bulk material be supplied to the customer under an agreement. You have the option of adequately labeling the bulk package."

### BAY RUM WITH ISOPROPYL ALCOHOL

During the present emergency, no action will be taken against bay rum containing isopropyl alcohol if the article is offered solely for cosmetic purposes and is labeled with a statement that it is manufactured from isopropyl alcohol.

TC-410—December 1, 1943

"In the past we have informed several manufacturers that in our opinion it would not be permissible to distribute under the name 'Bay Rum' an article manufactured from isopropyl alcohol in view of the fact that bay rum is a name which for many years has been associated with an article containing ethyl alcohol. We have carefully reconsidered this question in view of the present shortages and restrictions on the use of ethyl alcohol. In view of these con-

ditions it has been decided that no action will be taken during the present emergency against an article designated as bay rum which contains isopropyl alcohol, if the article is offered solely for cosmetic purposes and is labeled with a conspicuous statement showing that it is manufactured from isopropyl alcohol. This statement in our opinion should be so phrased and displayed as to clearly distinguish the article from that which was formerly on the market.



"Names such as 'West Indian Bay Rum' are obviously inappropriate for any except the true bay rum originating in the West

Indies and manufactured from ethyl alcohol. Use of such a title on the label must be regarded as constituting misbranding."

### BAKERY PRODUCTS CONTAINING THIAMINE, RIBOFLAVIN, NIACIN, AND IRON

The letter discusses a number of questions submitted concerning the labeling of various products containing added thiamine, riboflavin, niacin, and iron.

TC-411—January 10, 1944

"I understand that in conversations with members of this Administration you have asked a number of questions concerning the labeling of various bakery products containing added thiamine, riboflavin, niacin and iron.

"Replying concretely, if the white flour used in the preparation, for example, of doughnuts is enriched flour, it should be declared in the listed ingredients as 'enriched flour.' This statement in our opinion should appear with a degree of prominence comparable to that of the other ingredients. If no further representations with respect to enrichment are made on the label or elsewhere, it is our view that the product need not bear the additional statements required in the case of foods for special dietary uses.

"Where the ingredients to which we have referred are added directly to the doughnut mix in such amount as to equal the amounts which would be present if enriched flour had been used, we will not object to a label disclosure of that fact by a simple declaration in the list of ingredients of 'enriched flour.'

"As an alternative to an ingredient declaration of enriched flour, the ingredient declaration may be expanded to include the names of the added enriching ingredients such as thiamine, riboflavin, niacin and iron. In such case, however, it is our view that the additional statement called for by the regulations under foods for special dietary uses should appear on the label.

"I think you are aware of our conclusion that the term 'enriched' as a part of the name should be reserved for those foods in which the kind and amount of the enriching ingredients have been specified in the form of a standard promulgated under the Food, Drug, and Cosmetic Act or prescribed in a proposed order of the Administrator. Manufacturers are of course at liberty to employ other language, which is neither false nor misleading, to advise purchasers concerning the presence of the ad-

ded nutritional factors. In this event, however, the labels in our judgment must bear the information required in Section 403 (j). The statement pertaining to the proportion of the minimum daily requirements supplied should refer to a quantity of the food which can ordinarily be expected to be consumed by an average individual in a day, and the statement should be displayed with a degree of prominence comparable to that accorded the statement calling the purchaser's attention to the added nutritional factors."

"\* \* \* You refer to such foods as wheat bread, cracked wheat bread, and rye bread. It is likely that the first two foods fall within the scope of the standard proposed by the Administrator for 'Breads, and rolls or buns made with mixtures of flour, whole wheat flour, cracked wheat, crushed wheat,' specifications for which appear on page 10788 of the enclosed copy of the Federal Register of August 3, 1943. You will note that in the case of such breads the name of the food is derived from the names of the flour ingredients used—for example, a bread made from a mixture of white flour and whole wheat flour is designated as 'White and Whole Wheat Bread' if the predominating wheat ingredient is white flour, or vice versa if the whole wheat flour ingredient predominates. In the case of a bread made from a mixture of enriched flour and whole wheat flour we would not take exception to the designation of such a product as 'Whole Wheat and Enriched White Bread' if the whole wheat flour predominates or 'White (Enriched) and Whole Wheat Bread' if the white flour predominates. Products named in this manner, in our opinion, should meet the dietary labeling requirements.

"For those bread products requiring a list of ingredients under Section 403 (i) (2)—for example, rye bread—the presence of enriched flour should be made known by listing it in the ingredient statement. No greater prominence should be given to enriched flour in the ingredient list than to



the names of the other ingredients. Where thiamine, riboflavin, niacin, and iron are added to the dough mix in such amount as to equal the amounts which would be present if 'enriched flour' had been used, we will not object to a label disclosure of that fact by a simple declaration in the list of ingredients of enriched flour. \* \* \*

"The designation 'Enriched Rye Bread' should, in our opinion, not be employed since no definition for either enriched rye bread or enriched rye flour has as yet been announced. \* \* \*

"In the event that a manufacturer elects to hold forth his product as being of special dietary value by reason of vitamins and minerals, the total vitamin and mineral content of the finished product may serve as the quantitative basis for setting forth the information required under the special dietary food regulations.

"\* \* \* You have correctly interpreted our opinion that a baker cannot properly use the term 'Enriched Doughnuts.' You then inquire whether the label may bear a state-

ment such as 'these doughnuts (or sweet yeast goods) are now ENRICHED' or a statement such as 'made with ENRICHED flour.' We share with you the opinion that the statement 'these doughnuts are now ENRICHED' is little if any different from using the term 'Enriched Doughnuts' and carries with it the same objectionable features that encompass the use of the term 'enriched' as a part of the name. The propriety of the statement 'made with ENRICHED flour,' in our opinion, rests upon the manner in which it is used on a particular label. It is not difficult to visualize instances in which the size of type used, the position on the label or the use of other printing devices result in definitely misleading labels. Any probability of this can be avoided by restricting the reference to 'enriched flour' to its inclusion in the ingredient list in the same size and style of type used in listing the names of the other ingredients. You are familiar with our view that any reference to enrichment other than the declaration of 'enriched flour' in the ingredient list calls for the label information applicable to foods for special dietary uses."

### MERCURIAL PRESERVATIVES IN COSMETICS

Unless definite evidence is produced that none of the mercury in mercurial preservatives is absorbed through the skin and that no local skin irritation will result, cosmetic manufacturers will do well to refrain from employing such compounds.

TC-412—February 11, 1944

"We have \* \* \* an inquiry in regard to the use of Phenylmercuric Borate or Benzoate in cosmetic preparations. You mentioned concentrations of 1:10,000 (100 p.p.m.) and 1:20,000 (50 p.p.m.).

"Frankly the prospect of having millions of women use daily fairly large quantities of cosmetic creams containing 35 to 75 p.p.m. of mercury in a form having a potential systemic toxicity similar to that of bichloride of mercury is disturbing.

"Section 601 of the Food, Drug, and Cosmetic Act holds a cosmetic to be adulterated 'if it bears or contains any poisonous

or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.'

"It is our obligation to interpret this provision in the public interest. Unless proponents of the use of these toxic mercury preservatives can produce very definite evidence that none of the mercury is absorbed through the skin and that no local skin irritation will result, cosmetic manufacturers will do well to refrain from employing these compounds. This Administration is far from convinced that adequate evidence of harmlessness is now available."



## PHENOL

The letter discusses warnings on products containing phenol.

TC-413 (Modifies Item XI, "Carbolic acid in preparations for external application," in TC-14)—February 24, 1944

"Our present views on products containing phenol are that those articles which contain 1 per cent or less of phenol need not bear warnings of any kind. Those containing more than 1 per cent but not more than 2 per cent should bear warnings against

applying to large areas of the body and that a bandage should not be used when the product is applied to fingers and toes. If the product contains over 2 per cent phenol, we would ordinarily not regard it as safe for indiscriminate distribution unless it were offered for spot application or unless there was something unique about its composition which would cause us to modify our views."

---

## SULFONAMIDES

The letter discusses certain articles containing a sulfonamide which may be sold without the presentation of a doctor's prescription therefor.

TC-414—April 10, 1944

"So far as the Federal Food, Drug, and Cosmetic Act is concerned, we have not objected to the sale over-the-counter of adhesive absorbent gauze bandages containing small amounts of sulfonamides. Retail pharmacists may also properly sell to the lay public nose drops and a few new drugs for spot application containing small percentages of sulfonamides when the labeling for such articles bears adequate directions for use and warnings, and when the product is the subject of an effective new drug application as provided for in Section 505 of the Act. Sulfonamides for veterinary use which bear adequate directions for use

and appropriate warnings also may be sold to the lay public.

"Our suggestion to pharmacists has been that the solution of their problem is for them to obtain guaranties in one of the specific forms prescribed in the regulation under Section 303 (c) of the Act.

"With the exceptions to which we have referred, the sulfonamides and preparations containing them have not been found to be safe for indiscriminate distribution and in general such products bear the 'prescription legend' in lieu of adequate directions for use. They may not, in our opinion, legally be sold except to or upon the prescriptions of physicians or dentists."

---

## TONICS CONTAINING STRYCHNINE, IRON SALTS, AND ARSENIC

While iron salts may be sold as iron tonics, and strychnine in dosages less than 1/20 grain daily may be classed as a stimulant tonic, the Administration questions the advisability of using arsenic in any proportion.

TC-415—April 10, 1944

"We have your letter concerning warning statements to be included in labelings for preparations containing strychnine, arsenic and iron salts, which you refer to as 'tonics.'

"While iron salts may be sold as iron tonics, and strychnine in dosages less than 1/20 grain daily may be classed as a stimulant tonic, we question the advisability of recommending arsenic in any proportion for

indiscriminate sale for prolonged use.

"If strychnine in small doses were combined with an effective dose of ferrous sulfate (five grains three or four times daily), we would have no objection to the following warning statement because of the strychnine content: 'Warning: Do not take more than the dosage recommended as larger or more frequent doses may be dangerous and may cause serious injury.'"



## DRIED SKIM MILK—PUBLIC LAW 244, 78TH CONGRESS

Public Law 244, 78th Congress (H. R. 149), does not apply to any skim milk product other than dried skim milk.

TC-416—May 29, 1944

"Replying to your letter, H. R. 149\* does not apply to any skim milk product other than dried skim milk. It would be improper

to use the designations set up in this measure in the labeling of any food in which skim milk in any form other than dried skim milk is used as an ingredient."

## VITAMIN D

Preparations providing massive doses of vitamin D are considered unsafe for indiscriminate use.

TC-417—May 29, 1944

"We have your letter with regard to the unrestricted distribution of capsules of vitamin D containing 50,000 units of the active ingredient. You request our opinion on the suitability of this product for over-the-counter sale.

"There are two considerations which enter into a decision as to whether high potency vitamin D products are suitable for unrestricted distribution. First and foremost is the question of whether such products may be dangerous when used in accordance with the directions in the labeling. A review of the literature indicates that toxic effects in some individuals may be seen with doses in the neighborhood of 150,000 I. U. of vitamin D per day. It is to be noted, however, that there are many factors which affect the toxicity of such preparations. The process by which the vitamin D is produced, the vehicle in which the preparation is given, the calcium content of the diet, the season of the year, the activity of the patient, the duration of administration, the state of the

alimentary tract, the age, and the presence of preexisting pathology all play a role in determining whether a given dose or a given preparation may produce toxic effects in a given individual. Obviously, a lay person is not in a position to evaluate these various factors and from the standpoint of toxicity, it would not appear that such preparations can be safely used by the ordinary individual without medical supervision.

"The second consideration is the question of the value of these preparations in the treatment of arthritis. Medical opinion is divided on the question as to the efficacy of these preparations. Obviously, without more complete knowledge with regard to the exact status of vitamin D preparations in the treatment of arthritis, claims for their use in this condition may be misleading.

"In our opinion, high potency vitamin D preparations cannot be used safely or efficaciously by the ordinary lay person and distribution of such products should be restricted to sale by or on the prescription of a physician."

## EPINEPHRINE

No action will be presently taken against the indiscriminate distribution of preparations containing the equivalent of one per cent U.S.P. epinephrine if labeled with forthright directions and warnings and is applied by nebulizer.

TC-418 (Rescinds portion TC-361 referring to epinephrine)—  
July 12, 1944

"Soon after the Federal Food, Drug, and Cosmetic Act became effective we advised

the drug trade that in our opinion the sale of preparations of epinephrine bearing labeling inviting use by lay persons without the guidance of physicians would constitute a violation of the provisions of the law relat-

\* Public Law 244—78th Congress, approved March 2, 1944 (H.R. 149): " \* \* \* for the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), nonfat dry milk solids or defatted milk solids is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk

minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated. The term 'milk', when used herein, means sweet milk of cows."



ing to dangerous drugs. This opinion was based upon evidence available at that time.

"In the meantime there have been developments which cast doubt upon our original conclusion. There now appears to be a body of opinion that if such products are sold under labeling which is forthright in its directions, and particularly in its warnings against probable misuse, and if the product is employed in a type of nebulizer which produces an extremely fine mist without the formation of droplets and permits very small dosages to be administered, the product may be safely used without medical supervision.

"It will of course be our obligation to keep in touch with the development of facts by experts in the field, but for the present and until further notice we will not undertake legal proceedings against preparations of the sort which you distribute containing the equivalent of one per cent U. S. P. epinephrine if they are labeled to comply with the above suggestions. If you care to submit proposed revised labeling we shall be quite willing to consider it and to give you our view of the adequacy of the warnings and directions. If you adopt this course we suggest that a specimen of the nebulizer also be submitted."

### STRYCHNINE TONIC

The labeling of a tonic containing strychnine should clearly indicate that it is a strychnine tonic.

TC-419 (Revision of TC-415)—  
August 18, 1944

"We are of the opinion that the purchaser of a tonic is entitled to be informed in regard to the nature of the tonic, and we believe that the label of \* \* \* should clearly indicate that it is a strychnine tonic.

"While we are not prepared at the present time to take legal action on the claim that strychnine is a stimulant, there is considerable scientific evidence that strychnine does not exert a stimulant effect when given in dosages which can be regarded as safe other than when used under medical supervision."

### INTRAVENOUS SOLUTIONS

Large volume intravenous solutions should bear adequate directions for proper use under medical supervision.

TC-420—November 3, 1944

"We have your letter \* \* \* regarding the placing of directions for use in the labeling of large volume intravenous solutions.

"As you are aware, the revised regulations under Section 502 (f) (1) provide no exemption from the requirement that these solutions bear adequate directions for use. Since such products are administered under medical supervision, we would regard directions adequate for proper use under such supervision as meeting this requirement. For example, directions for the use of five per cent dextrose solution might well state

that the product should be warmed to body temperature and specify the rate of injection. In the case of less commonly used injections which are administered in large volume, it may be necessary to provide more detailed directions including indications for use. We believe that the guiding principle should be to keep in mind the extent to which the person who will administer the product is familiar with the various techniques and other factors relating to its administration, and to make the directions adequate for that person."

### RECTAL OINTMENTS CONTAINING BELLADONNA OR STRAMONIUM

Since an overdosage of extract of belladonna or stramonium may be dangerous, the labeling should provide detailed specific directions and warnings.

TC-421—November 10, 1944

"Since an overdosage of extract of belladonna or stramonium may be dangerous, the labeling should provide detailed specific directions. It is our opinion that even if the

directions are made so definite that there will be no question of safety in connection with the dose the labeling should still bear a warning that the dosage should be decreased if blurring of the vision or dryness



of the throat develops, and if these conditions develop after decreasing the dose, use of the article should be discontinued.

"We also believe that the labeling should

bear emphatic warning against use of the preparation for cases in which there is bleeding, such as 'Avoid using this preparation in case of bleeding since this may indicate a serious condition.' "

### PILLS AND TABLETS CONTAINING STRYCHNINE, ARSENIC, ETC., WITH IRON CARBONATE

Pills and tablets containing small proportions of ferrous carbonate combined with one or more of strychnine sulfate, nux vomica extract, arsenic trioxide, mercuric chloride, and laxative drugs such as aloin are irrational, and it is impossible to provide adequate directions for their use.

TC-422—December 6, 1944

There are on the market a number of preparations in pill and tablet form containing small proportions of ferrous carbonate combined with one or more of the following drugs: Strychnine sulfate, nux vomica extract, arsenic trioxide, mercuric chloride, and laxative drugs such as aloin.

In many instances the term "blaud" forms a part of the name of the article. Sometimes this term is given special prominence by appearing first in the designation.

The compositions of these pills and tablets are usually such that they cannot serve where iron therapy is indicated because the

dosage in which they can be safely administered, or the frequency and duration of administration is limited by the nature of the ingredients combined with the iron carbonate.

It is the opinion of the Food and Drug Administration that such items are irrational and that it is impossible to provide adequate directions for their use as required by the law.

It is suggested that pharmaceutical manufacturers who market such items give consideration to the advisability of abandoning their distribution.

### WARNING STATEMENTS

Particularly in the case of drugs packaged in such a way that all the labeling cannot be readily perused at the time of purchase, at least a summary of the mandatory information should appear on the outside of the package together with a reference to more detailed information elsewhere in the package.

TC-423—December 18, 1944

"We have your letter in which you discuss the question of the requirement of Section 502 (f) (2) of the Food, Drug, and Cosmetic Act. Because of the phraseology of Section 201 (m) defining the term 'labeling' you express the opinion, in effect, that the law requires that adequate warnings appear upon each separate piece of labeling material and in particular that they appear upon the carton.

"We doubt that the requirement that the labeling bear adequate warnings can be interpreted as requiring that such warnings must appear upon each part of the labeling.

However, Section 502 (c) requires that the mandatory information be conspicuously displayed so as to render it likely to be read and understood 'under customary conditions of purchase and use.' While there have as yet been no court decisions interpreting this section of the Act, it seems to us, particularly in the case of drugs packaged in such a way that all the labeling cannot be readily perused at the time of purchase, that at least a summary of the mandatory information should appear on the outside of the package together with a reference to more detailed information elsewhere in the package."



### DIRECTIONS FOR USE

Directions for use of drugs and devices, to be adequate, should inform the purchaser both how and for what purposes they may be used.

TC-424—December 20, 1944

"This refers to telephone conversation \* \* \* requesting an expression of this Administration on the question of whether the requirement of Section 502 (f) (1) of the Federal Food, Drug, and Cosmetic Act, defining drugs and devices as misbranded unless their labeling bears adequate directions for use, necessitates a statement in the labeling not only of how the drug is to be used but what it is to be used for.

"Paragraph (a) of the regulation under this section of the Act was embodied in the general regulations promulgated in December 1938. This paragraph has not been amended and is still in effect. As you know, it points out that directions for use may be inadequate for the reason, among others, that the labeling fails to bear directions for use in all the conditions for which the article is advertised or for which it is commonly and effectively used.

"It is our view that the fundamental purpose of this provision of the law is to insure that consumers will know what drugs and devices they buy are to be used for and how they are to be used. It is true that under some circumstances directions for use may

be adequate without any labeling indication of what the article is to be used for. Those instances would be where the article is generally known by consumers to be useful for a specific purpose. In such cases perhaps only directions as to how the article is to be used are required for adequacy.

"In emphasizing the requirement that directions for use should usually embody indications, I wish to point out that this requirement must not be construed as a pretext for the appearance in labeling of disease conditions in any manner which creates a misleading impression with respect to the efficacy of the article when used in those conditions. Certainly the provisions of Section 502 (a) as interpreted by those of 201 (n) are designed to insure that any reference to a disease condition shall be so presented and so qualified that consumers will not be misled. In certain instances, too, the information required in the labeling by the provisions of the second clause of Section 502 (f) for adequate warnings against probable misuse will have a direct bearing on the sufficiency of label statements in complying with the provisions of 502 (a), 201 (n), and 502 (f) (1)."

---

### AMPULS AND SOLUTIONS FOR INJECTION

Ampuls and solutions intended for injection should bear directions for use adequate for the guidance of physicians.

TC-425—January 5, 1945

"Your letter \* \* \* refers to the amended regulation under Section 502 (f) (1) of the Act, particularly as it applies to ampuls and solutions intended for injection.

"You are correct in your understanding that as a rule drugs which are not suitable for indiscriminate distribution either because of their toxicity or because of their method of use are entitled to exemption under the new regulation. Drugs intended for parenteral administration, however, are made the subject of a special requirement, paragraph (i) (2) on page 12256 of the Federal Register of October 10, 1944.

"In the formulation of this regulation, it seemed to us that for articles of this type, because of their importance, their harmful potentialities if they are improperly used, and particularly the impossibility of cor-

recting mistakes of administration it is necessary that directions be furnished to the physician. The limited investigations we have made indicate that physicians want directions for use for items in this class of drugs. It is not anticipated that directions on ampuled preparations should be addressed to the general public but rather to physicians. It is to be assumed that the physician has such necessary basic information as, for example, the technic of opening an ampul under aseptic conditions. The directions for use therefore may be supplied with this background in view. As an illustration, we think material which is intended for intramuscular injection only should bear a statement to this effect with perhaps a caution against intravenous administration, if such a route would be dangerous or otherwise undesirable."



### DIRECTIONS FOR USE

Directions for use for drugs, the uses of which are commonly known, may be adequate without mention upon their labeling of the purposes for which they are employed.

TC-426—January 22, 1945

"In re Section 502 (f) (1) of the Federal Food, Drug, and Cosmetic Act:

"We believe that aspirin and cascara sagrada are typical examples of articles which are generally known by the consumer to be useful for specific purposes, and directions for their use may therefore be ade-

quate without any labeling indication of what they are to be used for. This exception to the need for indicating in the labeling the conditions for which the article is to be used would also extend to several parenteral drugs, examples of which are morphine sulfate hypodermic tablets, dextrose and sodium chloride U. S. P., and ampuls of distilled water."

### NOTICE TO IMPORTERS OF PINEAPPLE PRODUCTS

Pineapple and sugar mixtures purporting to be pineapple preserves, but not complying with the standard, are illegal under any form of labeling, even if labeled as imitation pineapple preserve, and will be denied entry into country.

TC-427—April 14, 1945

In 1943 a number of importers of pineapple products were advised that various pineapple and sugar mixtures purporting to be pineapple preserves but which contained somewhat less soluble solids than the 68 per cent required by the standard of identity for pineapple preserves promulgated under the Food, Drug, and Cosmetic Act should either be made to conform to that standard by increasing the concentration of soluble solids or should be labeled as imitation pineapple preserve.

Further consideration of the matter in the light of recent court decisions has led us to conclude that products of this type are illegal under any form of labeling. It is not difficult to manufacture pineapple and sugar mixtures so as to contain not less than 68 per cent soluble solids and to otherwise conform to the standard for pineapple preserve in every particular.

On and after May 15, 1945, shipments of such illegal articles will be denied entry. Previously issued administrative opinions which are not in accord with this notice are hereby rescinded.

### GUARANTIES

False guaranties over printed or stamped signatures will be made the bases for criminal prosecution under Section 301 (h).

TC-428—May 5, 1945

Correspondent inquires whether the Administration accepts facsimile guaranty signatures on invoices as valid under the Food, Drug, and Cosmetic Act.

"As you know, there has been no court decision on the question as to whether a guaranty must be manually signed by the guarantor in order to afford protection or whether the guarantor's name may be printed or affixed by facsimile signature.

"It is our understanding that many firms have adopted as their signatures, for the purpose of guaranties stamped or printed on their invoices, facsimile signatures or the printed names under which such firms conduct their businesses.

"Unless and until court decisions hold such guaranties invalid it is our purpose to continue the practice followed in the past of referring cases involving such guaranties that are found to be false for prosecution under Section 301 (h) of the Act."



## INJECTIONS

The letter discusses directions for use for ampuls.

TC-429 (Note TC-420, TC-425)—  
May 21, 1945

"With your letter \* \* \* you sent us sample copies of labels for ampuls of Dextrose, U.S. P. 2½ per cent w/v in Isotonic Sodium Chloride Solution, and ampuls of Dextrose, U.S.P. 5 per cent w/v in Lactate-Ringer's Solution.

"On the former, to conform to the re-

quirements of the law that adequate directions appear in the labeling, you have stated 'Administer by hypodermaclysis or venoclysis with sterile equipment.'; on the latter, 'Administer by venoclysis with sterile equipment.' We regard these statements as satisfying the requirement of the Federal Food, Drug, and Cosmetic Act with reference to adequate directions for use."

## GLANDULAR PREPARATIONS

If glandular preparations have any efficacy their therapeutic results can be obtained only when used under the directions of a physician. Unless intended for parenteral use, they are entitled to exemption from labeling directions for use. If proven therapeutically useless, they will be misbranded because their labels cannot bear adequate directions for use.

TC-430—June 27, 1945

Correspondent quotes comment from a pharmaceutical manufacturer regarding the labeling of certain glandular preparations with adequate directions for use.

"In our previous letter we referred to glandular preparations which, so far as has been established, possess no useful therapeutic properties but for which there is a demand from some practitioners. We had in mind the idea that while the therapeutic value of such preparations has not been established, neither has it been shown that they are wholly devoid of value. In this indeterminate state of affairs, we have no disposition to interfere with the marketing of these products provided this is done in strict conformity with all applicable provisions of the Food, Drug, and Cosmetic Act.

"If these preparations have any efficacy their therapeutic results can be obtained only when they are used by or under the directions of a physician. Unless they are intended for parenteral use they are therefore entitled, through the regulations under Section 502 (f) (1), to exemption from labeling directions for use. When they are put up for parenteral use we have not insisted upon more specific directions than the statement of the route of administration; for example, 'For Hypodermic Use Only.' If further scientific evidence demonstrates conclusively that the products of this class are therapeutically useless, the Administration will have no alternative but to regard them as misbranded because, among other things, the labelings cannot bear adequate directions for drug use."

## EARACHE DROPS

Earache drops are inappropriate for self-medication.

TC-431—August 10, 1945

"\* \* \* We are not unmindful of the persuasive reason which you advance in support of your view that earache drops should be made available to relieve pain until a doctor can be consulted.

"Before entering into this project dealing with earache drops we made a careful survey of the field. Earache, as you know, may be a symptom of a fulminating infection of the middle ear which can progress very rapidly to mastoiditis. It is our considered judgment that because of the need for prompt medical treatment of such involve-

ment of the ear, it is contrary to the public interest to sell a product for the temporary relief of earache. Our long experience in the enforcement of food and drug laws convinces us that in a large number of cases the initial alarm of the patient which would prompt him to call a physician immediately would be allayed if through the use of ear drops the pain substantially decreased or disappeared.

"Because of this conclusion and because of the serious consequences likely to result therefrom, we must take the position that even under the labeling which you propose, the product would be illegal."



## GLANDULAR PREPARATIONS—ESTROGENS

Labeling of an estrogenic preparation in a manner indicating that the active ingredient has been derived from a natural source will violate the Act if the article has been prepared by a reduction of the estrone in the original material, or if estradiol has been added to it to increase its potency or its solubility in oil, or for any other reason.

TC 1-A—November 5, 1945

"This will reply to your inquiry regarding estrogenic hormones.

"The term 'natural estrogen' in our opinion means estrogenic material as it occurs in and is obtained from natural sources such as pregnant mares' urine, stallions' urine, human pregnancy urine, follicular fluids, etc., in contradistinction from estrogens synthetically produced, such as stilbestrol. Estradiol may be either a natural estrogen or it may be produced synthetically by hydrogenation of estrone. Its manner of production would determine whether or not it is a natural estrogen.

"Natural estrogen' is not recognized in any of the official compendia. There is no official standard for such an article. The proportions of estrone and estradiol in 'natural estrogen' doubtless vary with the source. It has been reported to us that the estrogenic material obtained from pregnant mares' urine ordinarily contains as much as 85-90 per cent of estrone. That, of course, does not mean that an article containing 90

per cent estrone is necessarily a 'natural estrogen.' Whether or not an estrogenic preparation is 'natural' depends upon its source, not upon the proportion of estrone contained in it."

"Labeling of an estrogenic preparation in a manner indicating that the active ingredient has been derived from a natural source such as pregnant mares' urine is regarded as a violation of the Federal Food, Drug, and Cosmetic Act if in fact the article has been prepared by a partial or complete reduction of the estrone in the original material, or if estradiol has been added to it to increase its potency or its solubility in oil, or for any other reason. Any evidence which demonstrates such manipulation, particularly inspectional evidence, will be sufficient to form the basis of legal action. There will be no disposition on the part of the Administration to limit its investigations in this field to chemical examinations to demonstrate the truth or falsity of labels of products of this kind with reference to their compositions."

## AMINO ACIDS

The letter discusses the use of amino acids in foods and drugs.

TC 2-A—November 5, 1945

"Amino acids cannot be added to any food for which a definition and standard has been promulgated because no provisions have been made for their use in any of the standards that are now effective. There are no prohibitions against the addition of amino acids to foods for which there are no definitions and standards other than those that relate to misbranding. A food to which amino acids have been added will be regarded as a food for special dietary use and must, therefore, be labeled to conform to the regulations under Section 403 (j). If an amino acid is added as a racemic mixture of two optical forms of which only one form can be utilized the ingredient statement must indicate that a racemic mixture is used, but in complying with the regulations under Section 403 (j) only the quantity of the active form of the acid shall be declared. Careful consideration must, of course, be

given to the provisions of the Act, and the labeling shall not be false and misleading in any particular. For your information in meeting this requirement I will discuss very briefly some of the pertinent facts relating to proteins.

"There is no evidence that amino acids added to foods will accomplish anything that cannot be accomplished by proper use of proteins as they occur naturally in our foods. Any need for adding amino acids to foods may, therefore, be viewed in the light of adequacy of protein intake. The most common recommendation for protein intake is one gram a day for each kilogram of body weight, or 70 grams for the average adult male. This figure is intended to provide a factor of safety of approximately 50 per cent in excess of the average minimum requirement of a person living on an ordinary mixed diet. Studies made by the Committee on Proteins of the National Research Coun-



cil during the past two years have shown that the average protein intake is about 100 grams a day and that more than half of this is from animal sources such as meat, fish, milk and eggs. Obviously one must look for very restricted diets if one expects to find persons on inadequate protein intakes. I do not believe there have been any reports which indicate that any particular segment of the population of this country needs supplementation with one or more amino acids.

"All of the protein requirements of the rat can be met by feeding ten amino acids which are called 'the essential amino acids.' It has been demonstrated that when these ten amino acids are given to man in quantities proportional to the individual requirements for the rat, they will meet the immediate protein requirements of man. There are studies under way to determine the quantities of each of these amino acids that must be consumed daily but no one knows the quantities needed for all of them at present. It has been reported that if the rat is fed the minimum quantity of each of the amino acids necessary for growth the amino acids will constitute 5.8 per cent of the rat's diet. If man requires the same relative quantities, approximately 35 grams of amino acids will be required daily for an adult using 3000 calories. In an average American diet supplying 3000 calories about one-third of the calories would be supplied by fat weighing approximately 100 grams. The remaining 2000 calories would be supplied by carbohydrate and protein weighing approximately 500 grams. Therefore the total dry weight of these food constituents consumed would be approximately 600 grams, and 5.8 per cent of 600 grams is 34.8 grams.

"On the basis of animal experimentation we may expect the carefully adjusted quantities of pure amino acids necessary to meet the minimum protein requirements of man to be about one-half of the present recommended protein intake. Indications are that requirements for individual amino acids range from about one to five grams a day. Obviously the addition of a few milligrams of an amino acid to the quantity of food that would be consumed in a day would serve no useful purpose.

"Protein hydrolysates may serve as a source of amino acids. These preparations may be so variable in composition that special consideration must be given to individual products with respect to their suitability as food ingredients and to their

declaration as food ingredients.

"If consideration is given to the inclusion of amino acids as one of the ingredients of standardized foods either by amendment of an existing definition and standard or the promulgation of a new definition and standard, attention should be given to the views expressed in the 'Statement of Policy of the Federal Security Agency under the Federal Food, Drug, and Cosmetic Act with respect to the Addition of Nutritive Ingredients to Foods' published in the Federal Register of July 3, 1943.

"The demonstrated value of amino acid preparations is at present largely limited to use for individuals who for various reasons are incapable of either consuming or digesting proteins present in ordinary food. The protein requirement of such individuals or a part of their requirement can be supplied temporarily by intravenous feeding or oral administration of amino acid preparations. Evidence of the need for oral administration of amino acids is still very limited. Protein requirements can be met by the use of synthetic amino acids or protein hydrolysates, or a combination of the two.

"Amino acid preparations for oral use fall in the category of Foods for Special Dietary Use but may also in some cases be subject to the drug provisions of the Act. Amino acid preparations offered for parenteral use fall in the category of New Drugs. With those preparations that consist in whole or in part of protein hydrolysates careful consideration must be given to the following:

"1. Uniformity of composition of the protein from which they are prepared.

"2. Uniformity of composition of the finished product.

"3. Absence of toxic products.

"4. Absence of products which may sensitize.

"5. Sterility.

"6. Absence of pyrogens.

"7. Adequacy of supply of biologically active amino acids.

"Amino acids made synthetically are available as racemic mixtures, that is, containing equal quantities of the two optically-active forms. Five of the essential amino acids have been shown to be biologically active only if present in the optical form which occurs naturally. In the acid hydrolysis of proteins some amino acids are partly racemized. In considering the quantities of amino acids that should be administered proper consideration must be given



to the quantities of amino acids present in a form in which they can be utilized.

"There is insufficient information to provide a basis for setting standards for amino acid dosage, but amino acid preparations intended to supply needs as food must supply these acids in substantial quantities. This is true whether the product is administered orally or parenterally. Recently there came to my attention a request for comment on a proposed label for a preparation of

amino acid tablets. The directions for use recommended taking three tablets a day. Three tablets were represented to contain a total of five milligrams of the ten essential amino acids with quantities of individual amino acids ranging from 0.1 to 1.0 milligram. Such tablets are obviously of no value. Preparations of protein hydrolysates may be so dilute that it would be impractical to administer an effective dose of amino acids."

### DDT IN FOODS

The letter discusses the status under the Act of foods containing DDT.

TC 3-A—November 5, 1945

DDT is by no means harmless. Its toxicity is less than that of several other common insecticides and it has many advantages over some insecticides that have long been in use. But the fact that it does have toxic properties should be fully recognized when it is used to protect growing crops or to prevent their infestation in storage or in the factory.

The Federal Food, Drug, and Cosmetic Act defines a food as adulterated if it contains any added poisonous or added deleterious substance *not required in the production of the food*. When the substance is so required the quantity present should be so restricted that the health of consumers is not jeopardized.

Under these provisions of the law DDT should not be employed on food crops or in the storage, handling, or manufacture of food unless it is required. In determining whether or not DDT is required there should be taken into account the availability of insecticides that are less toxic than DDT. There is grave question concerning the

propriety of the use of DDT on such crops as leafy vegetables since safer insecticides such as the pyrethrins and rotenone are available. No question is raised concerning the use of DDT on such fruits as apples and pears since it is less toxic than the other commonly used insecticides for these crops, such as lead arsenate and cryolite. In any event, the quantity of DDT used should be held to the minimum reasonably necessary for protection. For the present the Food and Drug Administration will not take action against apples and pears containing not more than 7 milligrams of DDT per kilogram of fruit.

The considerations applicable to the use of DDT in the production of crops consumed as human food should also be observed in the production of feed and forage crops for animals. DDT tends to accumulate in the fatty tissues of animals and in the fat of milk. The presence of DDT in fatty animal foods such as milk, meat, and their products would of course add to the hazards of consumption of fruits and vegetables upon which DDT is used.

### DIETHYLSTILBESTROL

The letter discusses the labeling of diethylstilbestrol preparations.

TC 4-A—November 5, 1945

"Your letter points out that at the time new drug applications were made effective for various forms of diethylstilbestrol, we suggested that the warning 'This is a potent drug and serious consequences may result if used other than under constant medical supervision' be placed prominently on the label. This warning was suggested in view of preliminary experience with large doses of this drug which suggested that untoward

effects on the blood and other serious complications might occasionally occur from its use.

"As you point out, experience during the last four years has demonstrated that with therapeutic dosages of this drug the toxic reactions have not been greater, either in number or severity, than those seen with therapeutically equivalent amounts of the natural estrogens. For this reason, we are inclined to agree with you that the warning



quoted above is no longer necessary on preparations of diethylstilbestrol in the usual dosage forms. We will not adversely criticize the label statement you propose, 'Physicians should familiarize themselves with the use of this product before it is admin-

istered. A circular giving full directions and contraindications will be furnished on request.' This we understand will be in addition to the conventional prescription legend 'Caution: To be dispensed only by or on the prescription of a physician.' "

### MONOCHLORACETIC ACID

Monochloracetic acid is a poisonous and deleterious substance. Beverages and other foods containing monochloracetic acid in any amount are adulterated.

TC 5-A—November 5, 1945

Certain manufacturers of solutions of monochloracetic acid are marketing this substance under representations which may readily give the impression that monochloracetic acid may safely and legally be used as an ingredient in beverages and other foods.

Monochloracetic acid is a poisonous and deleterious substance. This has been established by scientific investigation and has been confirmed in contested court cases.

The Food, Drug, and Cosmetic Act prohibits the addition of any poisonous or deleterious substance to a food "except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice" in which event a tolerance may be fixed by regulation. No tolerance for monochloracetic acid in beverages and other foods has been established since it has not been shown that its use is necessary.

That the addition to beverages and other foods in any amount of a poisonous and deleterious substance is an adulteration has been upheld by a Federal court in a case involving the addition of fluorine to beer. In that case the court explained to the jury that it was unimportant and irrelevant how much fluorine was added; that the question was not whether this added substance made the beer harmful but whether or not it was a harmful and deleterious substance which could be avoided by good manufacturing practice.

On December 29, 1941, the Food and Drug Administration, after a careful study of monochloracetic acid, issued a public notice entitled "Monochloracetic Acid an

Adulterant in Foods." Since that time a number of seizures have been made of beverages and other foods containing added monochloracetic acid. The Government's actions have been uniformly upheld by the courts. Very recently a large number of seizures were made of beverage bases containing this preservative, following acute illnesses occurring after consumption of the beverage prepared from them.

Seizures have been directed also against preservative solutions containing monochloracetic acid offered to food manufacturers. The manufacturers of two of these preparations contested the seizures. The court agreed with the Government's contention that monochloracetic acid is a poisonous and deleterious substance. At the request of the attorneys for the manufacturers the court found, over the objections of the Government on the ground of irrelevancy, that monochloracetic acid when present below certain concentrations would not render foods or beverages injurious, deleterious or unsafe for human consumption. This finding, however, is not pertinent to the issue, because the law prohibits the addition of any poison to a food unless that poison is required in its production or cannot be avoided by good manufacturing practice. The Food and Drug Administration has encountered no food which cannot be produced without the use of monochloracetic acid.

Legal action will be instituted on interstate shipments of any beverage or other food containing added monochloracetic acid. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal articles and criminal prosecution and injunction against the shippers of such articles.



### DRUGS DISPENSED ON PRESCRIPTIONS

The labeling of drugs dispensed pursuant to prescriptions must contain adequate warnings required by Section 502 (f) (2).

TC 6-A—February 14, 1946

With reference to the warning statement which you state you find upon packages of Thiouracil:

“Warning—This drug may impair resistance to infection. The physician should be consulted at the first sign of sore throat, fever, or any illness during treatment with Thiouracil,”

it is our opinion obliteration, destruction, or removal of this warning from the labeling when the article is received in interstate commerce and dispensed pursuant to a prescription would constitute a violation of the Federal Food, Drug, and Cosmetic Act.

Section 503 of the law provides exemption from certain of its requirements, including the listing of the name of the drug or the names of its active ingredients and the quantity of contents of the package. No provision is made for any exemption from the requirement of the law with reference

to the appearance in the labeling of such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

The article as you receive it from the manufacturers bears such warnings. The law specifically prohibits the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a drug if such act is done while the article is held for sale after shipment in interstate commerce and results in the article being misbranded.

If you transfer part or all of the contents of the manufacturer's package to another container we think you should label the new container with the warning which appears upon the manufacturer's package.

### CALCIUM COMPOUNDS

The labeling of calcium preparations intended for parenteral use should bear a warning that the article should not be injected intramuscularly in infants and young children.

TC 7-A—March 12, 1946

“We have your letter in regard to the need for warnings on labels of calcium compounds against their use for intramuscular injection in infants and children.

“Articles which have recently appeared in medical literature, together with information obtained by us from pediatricians, in-

dicate that the intramuscular injection of calcium salts may cause local undesirable reactions in infants. For this reason we have proposed that the labelings of calcium preparations intended for parenteral use bear a warning conspicuously displayed on the label that the article should not be injected intramuscularly in infants and young children.”

### MINERAL OIL SALAD DRESSINGS

Salad oils which contain mineral oil are adulterated under any form of labeling.

TC 8-A—April 4, 1946

“We have your letter in reference to the manufacture and sale of salad dressings containing mineral oil.

“Mineral oil is wholly without food value. Its substitution for food oils in common foods has always been regarded as an adulteration under any form of labeling.

“However, we have not heretofore taken

exception to the use under proper labels of mineral oil in foods intended for special dietary use by individuals required to restrict their caloric intake. In promulgating the regulations under Section 403 (j) of the Federal Food, Drug, and Cosmetic Act, recognition under fully informative labeling was given to the use of nonnutritive ingredients including mineral oil intended for such purposes.



"The regulations covering foods for special dietary use do not exempt such foods from the fundamental adulteration provisions of the Act. At the time the regulations were promulgated the available evidence as to the possible harmfulness of mineral oil in the diet was not regarded as sufficient to establish the illegality of such foods when adequately labeled. However, in an informal announcement made some time ago, reference was made to the probability that evidence of the deleterious character of mineral oil might be forthcoming which would make necessary a revision of the established policy. Recently in connection

with an injunction suit involving popcorn in which mineral oil had been substituted for a food fat customarily used, the findings of the court with respect to the deleterious character of mineral oil amply sustained this forecast.

"Under these circumstances the Administration has no alternative but to inform you that mineral oil salad dressings must be regarded as adulterated under the Federal Food, Drug, and Cosmetic Act under any form of labeling employed. It will be our purpose to investigate such traffic and refer the facts so obtained to the Department of Justice for appropriate legal action."

---







## STATEMENTS OF GENERAL POLICY OR INTERPRETATION

After passage of the Administrative Procedure Act in 1946, 60 Stat. 237, 5 U. S. C. 1001 *et seq.*, the Food and Drug Administration concluded that opinions which would otherwise have emanated as trade correspondence should thereafter be issued more formally. Since then, opinions of the Administration have been published in the Federal Register as "Statements of General Policy or Interpretation." The section numbers, "3.1," "3.2," etc., indicate the section numbers of Title 21, Chapter I, of the Code of Federal Regulations, under which these opinions are codified.

### NOTICE TO PACKERS OF CANNED OYSTERS

The notice discusses the packing of canned oysters. Pending adoption of standards of identity and for fill of container for all canned oysters, the Administration will apply the substantive provisions of the Act to canned oysters where the container is not as full of oysters as is practicable without injury to the quality or appearance of the product.

#### Section 3.1—February 3, 1947

Regulations fixing a standard of fill of container for canned oysters were promulgated on November 25, 1944 (21 C. F. R. 1944 Supp. 36.6). This standard requires that the drained weight of oysters, when the drained weight of such oysters in the can averages less than  $\frac{1}{2}$  ounce per oyster, shall be not less than 68 per cent of the water capacity of the can in which packed. For the No. 1 can, often referred to as the No. 1 eastern oyster can, having outside dimensions of diameter 2-11/16 inches and height 4.0 inches, a drained weight of about 7.5 ounces of oysters is required.

At the hearing which resulted in the promulgation of this standard, there was insufficient evidence to warrant findings of fact on which to base a standard of fill of container when the drained weight of oysters in a particular can averages  $\frac{1}{2}$  ounce or more per oyster. No standard for oysters of such size was established at that time.

It has recently come to our attention that some packers of canned oysters are now putting up large oysters, not subject to the requirements of the fill of container standard, so that the drained weight in many

instances is 5 ounces or even less for the No. 1 can. Although such canned oysters are not subject to the provisions of the fill of container standard they are subject to the substantive provisions of the Federal Food, Drug, and Cosmetic Act. Section 402 (b) (2) of this Act states that a food shall be deemed to be adulterated if any substance has been substituted wholly or in part therefor. Section 403 (d) of the Act provides that a food shall be deemed to be misbranded if its container is so made, formed or filled as to be misleading. It is our opinion that these sections apply to canned oysters if water, brine, or liquid draining from oysters during processing, replaces a quantity of oysters which should be added to fill the can.

It is the intention of this Agency to call a hearing as soon as practicable on proposals to adopt definitions and standards of identity and standards for fill of container for all canned oysters. In the meantime the Food and Drug Administration will apply the substantive provisions of the Act to canned oysters where the container is not as full of oysters as is practicable without injury to the quality or appearance of the product.



## NOTICE TO PACKERS AND SHIPPERS OF SHELLLED PEANUTS

Shelled peanuts in sacks, whether or not shipped in carload lots, should declare the name of the product, the net weight, and the name and place of business of the packer or distributor.

Section 3.2—June 2, 1947

Investigations by the Food and Drug Administration have shown that a number of interstate shipments of shelled peanuts in bags holding from approximately 100 to 125 pounds each have failed to bear labeling as required by the terms of the Federal Food, Drug, and Cosmetic Act.

Shelled peanuts in sacks, whether or not shipped in carload lots, should bear the following information required by the law on food in package form:

(a) The name of the product.

(b) An accurate statement of net weight.

(c) The name and place of business of the packer or distributor.

This information should be conspicuously set forth. It may be printed or stenciled on each bag or if desired, placed on tags which are securely attached to each bag.

The net weight marked on the bags must be the correct net weight of the peanuts at the time they are delivered to the carrier for interstate shipment. The tare weight of the bag should not be included in the weight declaration.

## NOTICE TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF GLANDULAR PREPARATIONS

It has been the opinion of the Administration that preparations of inert glandular materials intended for medicinal use should be labeled with the statement that there is no scientific evidence that the articles contain any therapeutic or physiologically active constituents.

The Administration is of the opinion that inert glandular materials may not be exempted from the requirements that they bear adequate directions for use; and that their labeling must accordingly include representations as to the conditions for which they are intended. Since any such representations would be false or misleading, such articles would be misbranded.

Inert glandular materials for parenteral use are subject to the same comment as applies to those intended for oral administration.

Section 3.3—March 12, 1948

Under date of December 4, 1941, in a notice to manufacturers of glandular preparations, the Food and Drug Administration expressed the opinion that preparations of inert glandular materials intended for medicinal use should, in view of the requirement of Section 201 (n) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1041; 21 U. S. C. 321 (n)), be labeled with a statement of the material fact that there is no scientific evidence that the articles contain any therapeutic or physiologically active constituents. Numerous preparations of such inert glandular materials were subsequently marketed with disclaimers of the type suggested. The term "inert glandular materials" means preparations incapable of exerting an action or effect of some significant or measurable benefit in one way or another, i.e., in the diagnosis, cure, mitigation, treatment, or prevention of disease, or in affecting the structure or any function of the body.

Manufacturers have heretofore taken advantage of Regulation (b) under Section 502 (f) of the Act (21 CFR, 2.106 (b)), permitting omission of directions for use where the so-called "prescription only" legend was placed upon the labels. This regulation was amended, effective October 10, 1945 (9 F.R. 12255-57). Among the conditions now authorizing the omission of directions for use, Regulation (b) (3) (Section 2.106), is the following: "Information adequate for the use of such drug \* \* \* by physicians, dentists, or veterinarians, as the case may be, is readily available." Obviously, information adequate for the use of a glandular preparation which is inert is not available to physicians, dentists, or veterinarians.

This Agency is of the opinion that inert glandular materials may not be exempted from the requirements of Section 502 (f) (1) that they bear adequate directions for use; and, accordingly, that their labeling must include, among other things, repre-



sentations as to the conditions for which such articles are intended to be used or as to the structure or function of the human body that they are intended to affect. Since any such representations offering these articles for use as drugs would be false or misleading, such articles will be considered to be misbranded if they are distributed for use as drugs.

The amended regulations provide also that in the case of drugs intended for parenteral administration there shall be no exemption from the requirement that their labelings bear adequate directions for use. Such inert glandular materials for parenteral use are therefore subject to the same comment as applies to those intended for oral administration. (Section 3, 60 Stat. 238; 5 U. S. C. 1002)

### NOTICE TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF DRUGS FOR INTERNAL USE WHICH CONTAIN MINERAL OIL

The Administration will regard as misbranded a drug for oral administration containing mineral oil, the labeling of which encourages its use in pregnancy or implies that it is for administration to infants.

It is the Administration's view that the law requires the labelings of such drugs to bear a warning against consumption other than at bedtime and against administration to infants.

#### Section 3.4—March 12, 1948

In the past few years research studies have altered medical opinion as to the usefulness and harmfulness of mineral oil in the human body. These studies have indicated that when mineral oil is used orally near mealtime it interferes with absorption from the digestive tract of provitamin A and the fat-soluble vitamins A, D, and K, and consequently interferes with the utilization of calcium and phosphorus, with the result that the user is left liable to deficiency diseases. When so used in pregnancy it predisposes to hemorrhagic disease of the newborn.

There is accumulated evidence that the indiscriminate administration of mineral oil to infants may be followed by aspiration of the mineral oil and subsequent "lipoid pneumonia."

In view of these facts, the Federal Security Agency will regard as misbranded under

the provisions of the Federal Food, Drug, and Cosmetic Act a drug for oral administration consisting in whole or in part of mineral oil, the labeling of which encourages its use in pregnancy or indicates or implies that such drug is for administration to infants.

It is also this Agency's view that the act requires the labelings of such drugs to bear a warning against consumption other than at bedtime and against administration to infants. The following form of warning is suggested: "*Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.*"

This statement of interpretation does not in any way exempt mineral oil or preparations containing mineral oil from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act. (Section 3, 60 Stat. 238; 5 U. S. C. 1002).

### NOTICE TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF GAUZE BANDAGES

Recent investigations have revealed that most manufacturers of gauze bandages have obtained the machinery needed for the individual wrapping of such bandages. It will be the purpose of the Administration to recommend legal action where the *United States Pharmacopoeia* packaging requirements are not complied with.

#### Section 3.5—March 12, 1948

The Twelfth Revision of the *United States Pharmacopoeia* established a packaging specification standard for Adhesive Absorbent Gauze (Adhesive Absorbent Compress)

which read: "Adhesive Absorbent Gauze must be packaged individually in such manner that the sterility is maintained until the individual package is opened for use, and the individual packages must be grouped in



a second protective container." This specification, with slight modifications in the wording, appears in the Thirteenth Revision of the *United States Pharmacopoeia*, which is now official.

At the time the standard was first promulgated representations were made to the Food and Drug Administration that, due to the existence of war priorities, it was impossible for manufacturers to obtain the machinery needed to wrap the bandages individually. In view of the priority situation existing at that time, the Administration informed manufacturers generally that until conditions changed no legal actions

would be inaugurated under the provisions of the Federal Food, Drug, and Cosmetic Act based solely on the failure to wrap adhesive gauze bandages individually.

Recent investigations have revealed that most manufacturers have obtained the machinery needed for the individual wrapping of such bandages or have been promised early delivery of such machinery. It will be the purpose of the Federal Security Agency to recommend legal actions in instances where United States Pharmacopoeia packaging requirements are not complied with after July 1, 1948. (Sec. 3, 60 Stat. 238; 5 U. S. C. 1002)

---

### NOTICE TO IMPORTERS OF PERUVIAN CANNED FISH PERUVIAN CANNED BONITA AND TUNA

The species of fish constituting the commercial bonito fishery in Peru is the same species of bonito that has been packed in the United States in small quantities and sold as bonito for many years.

The bonitos, *Sarda chilensis* and *Sarda velox*, are not classified as tuna, have never been legally labeled as tuna, and must be labeled as "bonito" or "bonito fish."

#### Section 3.6—October 20, 1948

In collaboration with the United States Department of State and officials of the Government of Peru, the Food and Drug Administration of the Federal Security Agency has made a study in Peru of the canning of bonito and tuna packed for exportation to the United States. The fish known in Peru as bonito constitutes a major portion of the pack. Representative specimens of Peruvian bonito have been identified as the species *Sarda chilensis*. This confirms previous information that the species of fish constituting the commercial bonito fishery in Peru is the same species of bonito that has been packed in this country in small quantities and sold as bonito for many years. Minor quantities of another bonito, *Sarda velox*, are apparently caught in Peruvian waters but do not enter the commercial pack to any significant degree. The bonitos, *Sarda chilensis* and *Sarda velox*, are not classified as tuna and under the provisions of the Federal Food, Drug, and Cosmetic Act have never been legally labeled as tuna, but must be labeled as

"bonito" or "bonito fish."

Two species of tuna, "skipjack" (*Katsuwonus pelamis*) and "yellowfin" (*Thunnus macropterus*), are commercially canned in Peru but constitute a relatively small proportion of the Peruvian pack of canned fish exported to the United States.

Information developed during the investigation in Peru shows that the bonito (*Sarda chilensis*) can be readily distinguished from the tunas. Consequently no difficulty should be encountered by packers in keeping separate the fish in the two classifications and in properly labeling the canned product before shipment.

The provisions of the Federal Food, Drug, and Cosmetic Act require that importations of canned bonito and canned tuna, when offered for entry into the United States, must bear labels designating the product as "bonito" or as "tuna," as the case may be. Shipments that are unlabeled or mislabeled when offered for entry must be detained and are subject to refusal of admission, with consequent exportation or destruction.

---



## NOTICE TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF VETERINARY PREPARATIONS AND ANIMAL FEEDS

A number of products, containing toxic substances, have been developed to promote fattening or effect other physiological changes in farm animals. When such substances are added to food, they render it adulterated.

Since these products are intended to affect the structure or function of the body of animals, and have not been previously used for such purposes, they are regarded as new drugs subject to the provisions of Section 505 of the Act.

### Section 3.7—November 30, 1948

A number of products have been developed to promote fattening, increase milk or egg production, or effect other physiological changes in farm animals. Many of these compounds contain as active ingredients substances the toxicity of which is known to be of a high order. For example, thiouracil, a very potent drug, has been proposed for use to promote fattening. When such substances are added to food they render the food adulterated under Section 402 (a) of the Federal Food, Drug, and Cosmetic Act.

The Federal Security Agency regards Sections 402 (a) (2) and 406 of the act as clear enunciations of congressional intent to deny the channels of interstate commerce to food containing added poisonous or deleterious ingredients which are un-

necessary in its production or which can be avoided by good manufacturing practice.

Since these compounds are intended to affect the structure or function of the body of animals and have not been previously used for such purposes, they are regarded as new drugs, requiring the submission of adequate evidence of their safety, as required by Section 505 of the act, before being marketed in interstate commerce.

In considering a new-drug application for a product intended to effect physiological changes in farm animals, the Federal Security Agency will regard the absence of satisfactory evidence showing that the meat or other food obtained from animals fed the drug is entirely free of any poisonous or deleterious ingredient resulting therefrom at the time of marketing as ground for refusal to make the application effective.

## TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF PENICILLIN-CONTAINING DRUGS FOR VETERINARY USE

The notice, with respect to labeling penicillin-containing drugs for veterinary use, is issued as a tentative guide to be used in conjunction with the penicillin regulations. Penicillin, under laboratory conditions, has pronounced potency against a wide range of organisms but is ineffective in infections caused by various other strains of organisms. Methods of administration and dosage, together with precautions, are set forth.

### Section 3.8—January 12, 1949

Since the release on October 5, 1945, of the notice to manufacturers and distributors of veterinary penicillin and a circular entitled "Indications, Directions and Precautions Suggested for Inclusion in the Labeling of Sodium and Calcium Penicillin for Veterinary Use" and the supplemental material released on April 25, 1946, much additional information has accumulated relative to the use of penicillin in animals. However, the knowledge concerning the efficacy and limitations of penicillin for treating various disease conditions of animals is far from being complete. Therefore this statement, which is intended to supersede previously released information on the labeling of penicillin-containing drugs for

veterinary use, is in the nature of a tentative guide to be used in conjunction with the penicillin regulations for labeling penicillin for veterinary use. As the knowledge of the efficacy and limitations of penicillin for treating animals is expanded there will be further releases relating to the labeling of such drugs. It is believed, however, that at the present time claims made in the labeling of penicillin intended for veterinary use should not exceed those suggested herein.

Penicillin, under laboratory conditions, has pronounced potency against a wide range of organisms, including the following of interest to veterinarians: most strains of streptococci, staphylococci, clostridia, corynebacteria, *Bacillus anthracis*, *Actinomyces*



*bovis*, *Erysipelothrix rhusiopathiae*, and leptospira. Penicillin is ineffective in infections caused by gram-negative bacilli, viruses, and occasional resistant strains of organisms which are usually regarded as susceptible to penicillin.

(a) *Indications.* There is conclusive scientific evidence establishing the therapeutic efficacy of penicillin for bovine mastitis caused by *Streptococcus agalactiae*. Good results have been reported in the use of penicillin for mastitis caused by strains of *Streptococcus dysgalactiae*. Results of treatment are no more than fair in mastitis caused by *Streptococcus uberis* and staphylococci; poor in cases caused by corynebacteria. Mastitis caused by colon bacilli does not respond to penicillin therapy. Reliable reports provide a supportive basis for recommending the use of penicillin for the following disease conditions: leptospirosis of dogs, osteomyelitis, peritonitis, strangles of horses, equine pneumonia, tetanus in the very early stage (with antitoxin), calf pneumonia, calf diphtheria, pyelonephritis in cattle, blackleg, malignant edema, anthrax in the very early stage, metritis, bovine actinomycosis, swine erysipelas in turkeys, and superficial infections of the skin caused by penicillin-sensitive organisms. It should be remembered that proper use of effective therapy depends on an accurate diagnosis of the disease condition to be treated.

(b) *Methods of administration*—(1) *By injection.* Deep intramuscular injection is the route of choice when using the parenteral forms of penicillin for systemic therapy. Subcutaneous injections are apt to be painful and are therefore usually avoided. When penicillin in oil or penicillin in oil and wax is injected care should be taken that the needle is not in a blood vessel before discharging the contents of the syringe.

(2) *By mouth.* Since penicillin is inactivated by gastric secretion, it cannot be given by mouth unless precautions are taken to neutralize the process in the stomach. This may be accomplished through the use of buffered penicillin tablets given at least  $\frac{1}{2}$  hour before and not less than 2 hours after eating. The therapeutic efficacy of these tablets will vary in different individuals and according to the amount of active penicillin absorbed. As a general rule, the amount of penicillin required for effective therapy when given by mouth is five times the amount required by injection. With the possible exception of small-animal practitioners, veterinarians will probably

find it impracticable to use penicillin in this form. Buffered penicillin tablets may be of value in some cases in which it is not possible to administer the drug by injection at the required intervals and in others after the disease has been brought under control by penicillin injections, and it is desirable to continue the use of the drug. The tablets may be given alone or as a supplement to parenteral therapy. In all serious conditions, however, parenteral administration is the recommended route.

(3) *By topical application.* Topical application includes direct injection of penicillin suspended in suitable vehicles into udders through the teat canal, into abscesses, joint capsules, body cavities, the spinal canal, and direct application to the skin and eyes. The underlying purpose of this method is to insure effective therapeutic concentrations of the drug in local areas of infection. In many instances it may be used as an adjunct to parenteral injections. However, after parenteral injection penicillin does not penetrate readily to the eyes, into spinal fluid, or, unless in extremely high unitage, into the milk. Therefore the topical method appears to be the only practicable one of treating local infections involving the eyes, spinal canal, or udder.

(c) *Dosage*—(1) *Systemic infections.* For therapy of systemic infections caused by most strains of penicillin-sensitive organisms a minimum of 2,000 units per pound of body weight should be administered, preferably by intramuscular injection. Further information concerning this recommendation may be obtained by request from the Food and Drug Administration. The required dosage of water-soluble salts of penicillin dissolved in proper aqueous solvents should be repeated every 3 to 4 hours to establish and maintain effective therapeutic concentrations of the drug in the body fluids and tissues. The necessary amount of penicillin in oil and wax should be given every 12 hours. The indicated quantity of procaine penicillin in oil or of certain of the newer certifiable repository penicillin products may be given as infrequently as once every 24 hours or longer. However, severe infections or infections caused by less sensitive organisms may require up to double the minimum dosage or more frequent injections or both. Since the objective of penicillin therapy is to bring the infection under control as quickly as possible, the minimum dosage or frequency of injection or both should be increased materially in all conditions known to be



caused by sensitive organisms if no definite indication of clinical improvement is noticed 12 to 14 hours after the initial injection.

(2) *Bovine Streptococcus agalactiae* mastitis. Effective treatment of udders infected with penicillin-sensitive organisms depends on maintaining therapeutically effective concentrations of penicillin in the area of infection. Available experimental data indicate that the following methods for introducing adequate amounts of the drug into infected quarters can be depended upon to overcome the infection in a majority (75% or more) of *Streptococcus agalactiae* mastitis cases:

(i) Aqueous solutions (sodium calcium, or crystalline penicillin dissolved in sterile distilled water):

(a) Inject 25,000 to 30,000 units under aseptic conditions through the teat canal into each infected quarter. Repeat after each milking or once every 12 hours until five to seven injections have been made. One repeat injection may be sufficient in the chronic form without induration.

(b) In cows producing up to 40 pounds of milk per day a total of 100,000 units per infected quarter administered as five injections of 20,000 units each at intervals of 12 hours or as four injections of 25,000 units each at intervals of 24 hours. In cows producing more than 40 pounds of milk per day or in acute cases a total of 200,000 units per infected quarter administered as four injections of 50,000 units each at intervals of 24 hours. It may be desirable to skip one milking after the last injection in the series to prolong a therapeutic concentration of penicillin in the treated quarters. Volume of vehicle should be adequate to favor immediate distribution throughout the cistern area. Usually 50 cc. is adequate.

(c) Large udders: First day, 200,000 units per infected quarter; second and third days, 100,000 units per infected quarter each day. Small to moderate-sized udders: First day, 100,000 units per infected quarter; second and third days, 50,000 units per infected quarter each day. All quarters infected with *Streptococcus agalactiae* at the time of drying off should be infused with 100,000 to 200,000 units sometime during the dry period, preferably during the interval between 2 weeks after the last milking and 3 weeks before parturition.

(ii) Emulsified solutions (soluble salts of penicillin dissolved in oil and water emulsi-

fied with lanolin derivatives): Inject 100,000 units under aseptic conditions through the teat canal into each infected quarter. Repeat treatment if subsequent bacteriological examination shows infection to be still present.

(iii) Bougies (25,000 or more units of sodium, calcium, potassium, or procaine penicillin in a milk-soluble base shaped in slender, elongated form to permit easy insertion into the milk cistern of the udder trough through the teat canal). Aseptically insert one bougie into each infected quarter after each milking for as long as the infection persists.

(iv) Oil and wax suspensions (calcium or crystalline penicillin in refined peanut or sesame oil and white wax) and ointments (calcium or crystalline penicillin in an ointment base suitable for udder instillation). In view of the scarcity of information concerning the use of such products, basic directions for use may be different in individual cases. Adequacy of directions as a whole depends primarily on the penicillin potency of each product and the nature of supportive data.

(3) *General*. Whenever practicable, accurate diagnosis should be established by identification of the causative organism. No case of mastitis should be considered cured unless bacteriological examination of the milk taken from treated quarters approximately 3 weeks after the last application of penicillin shows the absence of causative organisms. Augmenting penicillin therapy with proper surgical treatment yields best results when treating abscesses, empyema, suppurative arthritis, and infections of body cavities and joints caused by penicillin-sensitive organisms. Collections of pus should be removed prior to each local application of 25,000 to 50,000 units of penicillin in sterile aqueous solution two to three times every 24 hours. Sterile dressings, saturated with an aqueous solution containing at least 1,000 units of penicillin per milliliter, applied one or more times per day as the condition indicates, may be effective for treating superficial infections of the skin caused by penicillin-sensitive organisms. If indicated, supplement local therapy with systemic medication.

(d) *Precautions*. If reactions occur which cannot be adequately controlled and are more serious than the condition being treated, use of the drug should be discontinued.



## TO MANUFACTURERS, PACKERS, AND DISTRIBUTORS OF SALT SUBSTITUTES

The notice, with respect to the status of salt substitutes under the Act, states that such substitutes have been regarded in the past as special dietary foods; but they are also drugs, since they are employed in the mitigation and treatment of disease. Inasmuch as there is considerable doubt as to the safety of unrestricted use of any salt substitute in the presence of cardio-vascular-renal disease and a low sodium diet, the Federal Security Agency believes that each such substitute is a new drug within the meaning of Section 201 (p) of the Act.

Section 3.9—March 2, 1949

The recent reported poisonings from salt substitutes containing lithium chloride have focused attention upon this entire field. Salt substitutes have been regarded in the past as special dietary foods. They are also drugs, since they are employed in the mitigation and treatment of disease.

There is considerable doubt as to the safety of unrestricted use of any salt sub-

stitute in the presence of cardio-vascular-renal disease and a low sodium diet.

Consequently, the Federal Security Agency believes that each salt substitute is a new drug within the meaning of Section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of each salt substitute should be discontinued until a new-drug application has been filed and has become effective with respect to the substitute.

---

## NOTICE TO MANUFACTURERS AND USERS IN FOOD PRODUCTS OF MONOSODIUM GLUTAMATE

In the light of further information, the Food and Drug Administration is not disposed to maintain the position that monosodium glutamate be designated as an artificial flavoring on the labels of foods to which it is added. Its presence should be declared on the labels of unstandardized foods by its common or usual name, monosodium glutamate.

If in any case the addition of the product conceals damage or inferiority, or makes the article appear to be better than it is, the article would be adulterated regardless of labeling.

Section 3.10—May 20, 1949  
(corrected June 2, 1949)

In the light of the information now before the Food and Drug Administration on the manner of use of monosodium glutamate in foods, this Agency is not disposed to maintain the position previously expressed by it on April 11, 1940, in a trade correspondence letter designated as TC 233 that monosodium glutamate be designated as an artificial flavoring on labels of foods to which it is added. Where it is used as an ingredient in a food for which a standard of identity has not been promulgated under the Federal Food, Drug, and Cosmetic Act, its presence should be declared on the label

by its common or usual name, monosodium glutamate, in compliance with Section 403 (i) (2) of the act. Since none of the standards of identity for food so far promulgated under Section 401 provide for the inclusion of monosodium glutamate as an optional ingredient, this substance may not be used in such standardized foods unless and until the appropriate standards are amended after hearing. If in any case the addition of monosodium glutamate has the effect of concealing damage or inferiority, or of making the article appear to be of better or greater value than it is, the article would be classed as adulterated regardless of labeling.

---



# TABLE OF REFERENCES

## FROM LAW TO INTERPRETATIONS

This part lists under each subsection of the Federal Food, Drug, and Cosmetic Act (1) references to the applicable regulations promulgated by the Food and Drug Administration, (2) citations to all relevant cases decided under the Food and Drugs Act of 1906, (3) citations to the decisions rendered under the Federal Food, Drug, and Cosmetic Act, (4) citations to pertinent decisions rendered by the courts under the Federal Trade Commission Act, (5) citations to pertinent opinions of the Attorney General of the United States, and (6) citations to the Trade Correspondence and Statements of General Policy or Interpretation which deal with the subsection. In the event a question presents itself with respect to any particular subsection of the statute, this portion of the book is designed to furnish a lead to all relevant material bearing on or dealing with the subsection.

The full text of each decision rendered under the Federal Food, Drug, and Cosmetic Act, and of each Trade Correspondence and Statement of General Policy or Interpretation, may be readily located in this book by reference to the page cited immediately following the listing of the case or ruling.

Other citations and abbreviations for the most part will be readily recognizable. Citations of regulations are to "CFR," meaning the official Code of Federal Regulations, and "F.R.," meaning the official Federal Register. Citations of court decisions are to "U. S.," meaning the official United States Supreme Court Reports, and to "Fed.," "F. 2d," "F. Supp.," and "F.R.D.," all publications of the West Publishing Company.

### SECTION 1

#### Regulations

21 CFR, Cum. Supp., 2.1

---

### SECTION 201(a)

#### Trade Correspondence

TC-250, April 25, 1940, page 666

---

### SECTION 201(b)

#### Pertinent 1906 Act Decisions

United States v. Tucker  
188 Fed. 741 (S.D. Ohio, 1911)

McDermott v. State of Wisconsin  
228 U.S. 115 (1913)

Weeks v. United States  
245 U.S. 618 (1918)

United States v. 492 Cases \* \* \* Orange Juice  
20 F. Supp. 520 (E.D. La., 1937), affirmed 96 F. 2d 972 (C.C.A. 5)



## SECTION 201 (b)—continued

- United States v. Great Atlantic & Pacific Tea Co.  
92 F. 2d 610 (C.C.A. 2, 1937), 113 A.L.R. 961
- United States v. Nesbitt Fruit Products, Inc.  
96 F. 2d 972 (C.C.A. 5, 1938), affirming 20 F. Supp. 520 (E.D. La.)

## 1938 Act Decisions

- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. 184 Barrels Dried Whole Eggs, page 59  
53 F. Supp. 652 (E.D. Wis., 1943)
- United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- United States v. 7 Barrels, etc., "Spray Dried Whole Egg," page 85  
141 F. 2d 767 (C.C.A. 7, 1944)
- United States v. Marshall Kirby & Co., Inc., page 85  
141 F. 2d 767 (C.C.A. 7, 1944)
- Arner Co., Inc., et al. v. United States, page 99  
142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)
- Rubenstein v. United States, page 460  
153 F. 2d 127 (App. D.C., 1946)
- United States v. Sullivan, page 319  
67 F. Supp. 192 (M.D. Ga., 1946)
- United States v. Phelps Dodge Mercantile Co., page 189  
157 F. 2d 453 (C.C.A. 9, 1946), certiorari denied 330 U.S. 818 (1947)
- Sullivan v. United States, page 334  
161 F. 2d 629 (C.C.A. 5, 1947)
- United States v. Walsh, trading as Kelp Laboratories, page 337  
331 U.S. 432 (1947)
- United States v. Sullivan, page 350  
332 U.S. 689 (1948)
- 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
168 F. 2d 361 (C.C.A. 6, 1948)

## Trade Correspondence

- |                                  |                                  |
|----------------------------------|----------------------------------|
| TC-183, March 15, 1940, page 640 | TC-246, April 25, 1940, page 665 |
| TC-192, March 15, 1940, page 643 | TC-250, April 25, 1940, page 666 |

## SECTION 201(e)

## 1938 Act Decisions

- United States v. Buffalo Pharmacal Co., Inc. et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Dotterweich, page 278  
320 U.S. 277 (1943)

## Opinions of the Attorney General

- 26 Ops. Att'y. Gen. 546, March 27, 1908

## SECTION 201(f)

## Pertinent 1906 Act Decisions

- United States v. Thirteen Crates of Frozen Eggs  
208 Fed. 950 (S.D. N.Y., 1913), affirmed 215 Fed. 584 (C.C.A. 2)
- Weeks v. United States  
224 Fed. 69 (C.C.A. 2, 1915)



## SECTION 201 (f)—continued

United States v. 52 Drums Maple Syrup  
110 F. 2d 914 (C.C.A. 2, 1940)

## 1938 Act Decisions

United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942

United States v. Harold Hain (Hain Pure Food Co.), page 265  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944

In re United States, page 480  
140 F. 2d 19 (C.C.A. 5, 1943)

Joseph v. United States, page 303  
145 F. 2d 74 (C.C.A. 9, 1944), certiorari denied 323 U.S. 776 (1944)

United States v. 24 Cans, etc., Butter et al., page 156  
148 F. 2d 365 (C.C.A. 5, 1945), certiorari denied 326 U.S. 752 (1945)

United States v. 12 Bottles of Esterex, page 523  
(E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949

## Trade Correspondence

TC-149, March 7, 1940, page 627	TC-272, May 7, 1940, page 676
TC-224, April 11, 1940, page 657	TC-384, May 29, 1942, page 725

## SECTION 201(g)

## Pertinent 1906 Act Decisions

United States v. Four Boxes of Mulford's Wintergreens  
(N.D. N.Y., 1914) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 592

Bradley v. United States  
264 Fed. 79 (C.C.A. 5, 1920)

Goodwin et al. v. United States  
2 F. 2d 200 (C.C.A. 6, 1924)

United States v. 23 7/12 Dozen Bottles \* \* \* "Lee's Save the Baby"  
44 F. 2d 831 (D. Conn., 1930)

United States v. Eleven Cartons of \* \* \* "Vapex"  
59 F. 2d 446 (D. Md., 1932)

United States v. 48 Dozen Packages \* \* \* Gauze Bandage  
94 F. 2d 641 (C.C.A. 2, 1938)

## 1938 Act Decisions

United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942

United States v. Harold Hain (Hain Pure Food Co.), page 265  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944

United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)

United States v. Sullivan, page 319  
67 F. Supp. 192 (M.D. Ga., 1946)

United States v. Paddock, page 463  
68 F. Supp. 407 (W.D. Mo., 1946)

Alberty v. United States, page 332  
159 F. 2d 278 (C.C.A. 9, 1947)

United States v. 150 Packages, etc., Labeled In Part Bush Mulso Tablets et al.  
83 F. Supp. 875 (E.D. Mo., 1947)

United States v. 9 Bottles \* \* \* "Colusa Natural Oil," etc., page 218  
78 F. Supp. 721 (N.D. Iowa, 1947)

United States v. Crescent-Kelvan Company et al., page 359  
164 F. 2d 582 (C.C.A. 3, 1948)



## SECTION 201 (g)—continued

## Trade Correspondence

TC-21, Feb. 9, 1940, page 580	TC-146, March 7, 1940, page 625
TC-24, Feb. 9, 1940, page 581	TC-163, March 14, 1940, page 633
TC-26, Feb. 9, 1940, page 581	TC-187, March 15, 1940, page 641
TC-40, Feb. 9, 1940, page 585	TC-220, March 21, 1940, page 655
TC-42, Feb. 12, 1940, page 586	TC-229, April 11, 1940, page 659
TC-61, Feb. 15, 1940, page 593	TC-245, April 25, 1940, page 665
TC-130, March 7, 1940, page 620	TC-260, April 25, 1940, page 671

## SECTION 201(h)

## 1938 Act Decisions

- United States v. Harold Hain (Hain Pure Food Co.), page 265  
 (S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug,  
 and Cosmetic Act, Drugs and Devices (No. 919) Issued October, 1944
- United States v. Crown Rubber Sundries Co. et al., page 330  
 67 F. Supp. 92 (N.D. Ohio, 1946)
- United States v. One Device, etc., "Tox Eliminator," etc., page 199  
 160 F. 2d 194 (C.C.A. 10, 1947)

## Trade Correspondence

TC- 41, Feb. 12, 1940, page 585	TC-112, Feb. 29, 1940, page 613
TC-100, Feb. 21, 1940, page 609	TC-113, Feb. 29, 1940, page 613
TC-105, Feb. 29, 1940, page 611	TC-114, Feb. 29, 1940, page 614
TC-109, Feb. 29, 1940, page 612	TC-160, March 14, 1940, page 631
TC-110, Feb. 29, 1940, page 613	TC-260, April 25, 1940, page 671
TC-111, Feb. 29, 1940, page 613	TC-316, Aug. 20, 1940, page 693

## SECTION 201(i)

## Trade Correspondence

TC- 21, Feb. 9, 1940, page 580	TC- 60, Feb. 15, 1940, page 593
TC- 24, Feb. 9, 1940, page 581	TC- 61, Feb. 15, 1940, page 593
TC- 26, Feb. 9, 1940, page 581	TC-109, Feb. 29, 1940, page 612
TC- 39, Feb. 9, 1940, page 585	TC-146, March 7, 1940, page 625
TC- 40, Feb. 9, 1940, page 585	TC-170, March 14, 1940, page 635
TC- 42, Feb. 12, 1940, page 586	TC-245, April 25, 1940, page 665
	TC-349, Dec. 28, 1940, page 707

## SECTION 201(j)

## 1938 Act Decisions

- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
 131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Crescent-Kelvan Company et al., page 359  
 164 F. 2d 582 (C.C.A. 3, 1948)

## SECTION 201(k)

## 1938 Act Decisions

- Arner Co., Inc., et al. v. United States, page 99  
 142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)



## SECTION 201 (k)—continued

## Trade Correspondence

TC- 12, Reprinted June 1941, page 568	TC- 45, Feb. 12, 1940, page 587
	TC-102, Feb. 29, 1940, page 610

## SECTION 201(1)

## Trade Correspondence

TC-12, Reprinted June 1941, page 568

## SECTION 201(m)

## Regulations

21 CFR, Cum. Supp., 2.2

## Pertinent 1906 Act Decisions

United States v. American Druggists' Syndicate  
186 Fed. 387 (E.D. N.Y., 1911)

United States v. Eleven Packages of B. & M. External Remedy  
(D. N.H., 1922), White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1059

United States v. 17 Bottles \* \* \* Labeled in Part "B. & M."  
55 F. 2d 264 (D. Md., 1932)

## 1938 Act Decisions

United States v. Royal Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)

United States v. Research Laboratories, Inc., page 15  
126 F. 2d 42 (C.C.A. 9, 1942), certiorari denied 317 U.S. 656 (1942)

United States v. Royal Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)

United States v. Howard-Iowa Products Co., page 274  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1010) Issued March 1945

United States v. Seven Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)

United States v. 1 Dozen Bottles \* \* \* "Boncquet Tablets," page 122  
146 F. 2d 361 (C.C.A. 4, 1944)

United States v. Alberty, page 315  
65 F. Supp. 945 (S.D. Calif., 1946)

United States v. Paddock, page 462  
67 F. Supp. 819 (W.D. Mo., 1946)

United States v. Kordel, page 328  
66 F. Supp. 538 (N.D. Ill., 1946)

United States v. Paddock, page 463  
68 F. Supp. 407 (W.D. Mo., 1946)

Alberty v. United States, page 332  
159 F. 2d 278 (C.C.A. 9, 1947)

United States v. One Device, etc., "Tox Eliminator," etc., page 199  
160 F. 2d 194 (C.C.A. 10, 1947)

United States v. Kordel, page 343  
164 F. 2d 913 (C.C.A. 7, 1947)

Urbeteit v. United States, page 212  
164 F. 2d 245 (C.C.A. 5, 1947)

Kordel v. United States, page 382  
335 U.S. 345 (1948)

United States v. Urbeteit, etc., page 249  
335 U.S. 355 (1948)

United States v. Dr. Charles Kaadt and Dr. Peter S. Kaadt, page 388  
171 F. 2d 600 (C.A. 7, 1948)



## SECTION 201 (m)—continued

- Urbeteit, etc. v. United States, page 521  
172 F. 2d 386 (C.A. 5, 1949)
- United States v. Two Articles of Device \* \* \* "Tox Eliminator," etc., page 529  
(E.D. Okla., 1949)
- United States v. Urbeteit, etc., page 560  
336 U.S. 804 (1949)
- United States v. Four Devices, Labeled in Part "Color-Therm" etc., and Franklin D. Lee  
(C.A. 10, 1949)
- Urbeteit v. United States  
(C.A. 5, 1949)

## Trade Correspondence

- |                                      |                                 |
|--------------------------------------|---------------------------------|
| TC-12, Reprinted June 1941, page 568 | TC-310, Aug. 20, 1940, page 690 |
|                                      | TC-423, Dec. 18, 1944, page 744 |

## SECTION 201(n)

## Regulations

- 21 CFR, Cum. Supp., 2.3

## Pertinent 1906 Act Decisions

- United States v. Dr. David Roberts Veterinary Co., Inc., et al.  
104 F. 2d 785 (C.C.A. 7, 1939)
- United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
32 F. Supp. 958 (S.D. N.Y., 1940)

## 1938 Act Decisions

- United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942
- United States v. 11¼ Dozen Packages \* \* \* "Mrs. Moffat's Shoo Fly Powders for Drunkenness," page 8  
40 F. Supp. 208 (W.D. N.Y., 1941)
- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. Seven Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets et al., page 107  
142 F. 2d 107 (C.C.A. 7, 1944), certiorari denied 323 U.S. 731 (1944)
- United States v. Elmer J. Dailey (Dailey's Laboratories), page 299  
(S.D. Calif., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1326) Issued November 1945
- United States v. 12 Bottles of Esterex, page 523  
(E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949
- Research Laboratories, Inc. v. United States, page 227  
167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948)
- Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States, page 370  
169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)

## Of Incidental Interest

- Pinkus v. Reilly  
170 F. 2d 786 (C.A. 3, 1948), certiorari granted May 16, 1949



## SECTION 201 (n)—continued

## Trade Correspondence

TC- 12, Reprinted June 1941, page 568	TC-352, Jan. 22, 1941, page 709
TC- 90, Feb. 21, 1940, page 606	TC-354, Feb. 3, 1941, page 710
TC-190, March 15, 1940, page 642	TC-355, Feb. 12, 1941, page 711
TC-193, March 15, 1940, page 643	TC-357, April 17, 1941, page 712
TC-313, Aug. 20, 1940, page 692	TC-360, April 24, 1941, page 713
TC-321, Sept. 5, 1940, page 695	TC-376, Dec. 10, 1941, page 721
TC-324, Sept. 5, 1940, page 697	TC-378, Dec. 29, 1941, page 722
TC-337, Sept. 5, 1940, page 702	TC-379, Jan. 23, 1942, page 723
TC-338, Sept. 5, 1940, page 703	TC-385, May 29, 1942, page 725
TC-343, Dec. 13, 1940, page 704	TC-388, July 27, 1942, page 726
TC-344, Dec. 13, 1940, page 705	TC-401, April, 19, 1943, page 734
TC-348, Dec. 18, 1940, page 707	TC-424, Dec. 20, 1944, page 745

## Statements of General Policy or Interpretation

21 CFR 3.3, March 12, 1948, page 756

## SECTION 201(o)

## Pertinent 1906 Act Decisions

United States v. 17 Bottles \* \* \* "B. & M."  
55 F. 2d 264 (D. Md., 1932)

## SECTION 201(p)

## Regulations

21 CFR, Cum. Supp., 2.108

## Trade Correspondence

TC-400, April 7, 1943, page 733

## Statements of General Policy or Interpretation

21 CFR 3.9, March 2, 1949, page 762

## SECTION 301(a)

## Pertinent 1906 Act Decisions

United States v. Mayfield et al.  
177 Fed. 765 (N.D. Ala., 1910)  
United States v. Buffalo Cold Storage Co.  
179 Fed. 865 (W.D. N.Y., 1910)  
Hall-Baker Grain Co. v. United States  
198 Fed. 614 (C.C.A. 8, 1912)  
United States v. J. L. Hopkins & Co.  
199 Fed. 649 (E.D. N.Y., 1912)  
Philadelphia Packing Co. v. United States  
202 Fed. 150 (C.C.A. 3, 1913)  
Dr. J. L. Stephens Co. v. United States  
203 Fed. 817 (C.C.A. 6, 1913)  
United States v. Sprague et al.  
208 Fed. 419 (E.D. N.Y., 1913)



## SECTION 301 (a)—continued

- United States v. Bowers  
(E.D. Tenn., 1916) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 763
- Union Dairy Co. v. United States  
250 Fed. 231 (C.C.A. 7, 1918)
- W. B. Wood Mfg. Co. v. United States  
292 Fed. 133 (C.C.A. 8, 1923)
- United States v. Alaska Consol. Canneries et al.  
2 F. 2d 614 (W.D. Wash., 1924)
- United States v. Lesser et al.  
66 F. 2d 612 (C.C.A. 2, 1933)
- George A. Breon & Co., Inc. v. United States  
74 F. 2d 4 (C.C.A. 8, 1934)
- Taylor et al. v. United States  
80 F. 2d 604 (C.C.A. 5, 1936), certiorari denied 297 U.S. 708 (1936)
- United States v. Feeders' Supply & Mfg. Co.  
15 F. Supp. 385 (W.D. Mo., 1936)
- United States v. Kraft Phenix Cheese Corporation  
18 F. Supp. 60 (S.D. N.Y., 1936)
- United States v. Great Atlantic & Pacific Tea Co.  
92 F. 2d 610 (C.C.A. 2, 1937), 113 A.L.R. 961
- United States v. William H. Rorer, Inc.  
27 F. Supp. 671 (E.D. Pa., 1936)
- Alberty v. United States  
91 F. 2d 461 (C.C.A. 9, 1937)
- Strong, Cobb & Co., Inc. v. United States  
103 F. 2d 671 (C.C.A. 6, 1939)
- United States v. Lee  
107 F. 2d 522 (C.C.A. 7, 1939), certiorari denied 309 U.S. 659 (1940)
- United States v. S. B. Penick & Co. et al.  
136 F. 2d 413 (C.C.A. 2, 1943)

## 1938 Act Decisions

- United States v. Norman C. Heron (N.C. Heron Co.), page 253  
(S.D. Calif., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 345) Issued March 1942
- United States v. Royal Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)
- United States v. Commercial Creamery Co., page 257  
43 F. Supp. 714 (E.D. Wash., 1942)
- United States v. Buffalo Pharmacal Co., Inc. et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Royal Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)
- Empire Oil & Gas Corporation et al. v. United States, page 270  
136 F. 2d 868 (C.C.A. 9, 1943)
- Helco Products Co., Inc. v. McNutt et al., page 477  
137 F. 2d 681 (App. D.C., 1943)
- United States v. Greenbaum, page 275  
138 F. 2d 437 (C.C.A. 3, 1943), 152 A.L.R. 751
- United States v. Dotterweich, page 278  
320 U.S. 277 (1943)
- United States v. Swift & Co. et al., page 449  
53 F. Supp. 1018 (M.D. Ga., 1943)
- United States v. Harold Hain (Hain Pure Food Co.), page 265  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944
- United States v. Howard-Iowa Products Co., page 274  
(S.D. Iowa, 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1010) Issued March 1945
- United States v. Sekov Corporation and Hazel Ruth Vokes (Sekov Studios), page 448  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1001) Issued March 1945
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)



## SECTION 301 (a)—continued

- United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)
- Triangle Candy Co. et al. v. United States, page 294  
144 F. 2d 195 (C.C.A. 9, 1944), 155 A.L.R. 903
- Joseph v. United States, page 303  
145 F. 2d 74 (C.C.A. 9, 1944), certiorari denied 323 U.S. 776 (1944)
- United States v. Lazere, page 451  
56 F. Supp. 730 (N.D. Iowa, 1944)
- United States v. Elmer J. Dailey (Dailey's Laboratories), page 299  
(S.D. Calif., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1326) Issued November 1945
- United States v. Saunders Mills, Inc., Clarence M. Saunders, and Evelyn M. Crow, page 454  
(S.D. Ohio, 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8587) Issued July 1946
- United States v. Gerber Products Co., page 306  
(W.D. Mich., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7808) Issued January 1946
- United States v. Commonwealth Brewing Corporation and Leo Kaufman, page 310  
(D. Mass., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7926) Issued March 1946
- United States v. G. Fred Obrecht et al., page 456  
(D. Md., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8894) Issued February 1947
- Rubenstein v. United States, page 460  
153 F. 2d 127 (App. D.C., 1946)
- United States v. Alberty, page 315  
65 F. Supp. 945 (S.D. Calif., 1946)
- United States v. Douglas, page 318  
155 F. 2d 894 (C.C.A. 7, 1946)
- United States v. Paddock, page 462  
67 F. Supp. 819 (W.D. Mo., 1946)
- United States v. Kordel, page 328  
66 F. Supp. 538 (N.D. Ill., 1946)
- United States v. Crown Rubber Sundries Co. et al., page 330  
67 F. Supp. 92 (N.D. Ohio, 1946)
- United States v. Paddock, page 463  
68 F. Supp. 407 (W.D. Mo., 1946)
- Alberty v. United States, page 332  
159 F. 2d 278 (C.C.A. 9, 1947)
- Hygrade Food Products Corporation v. United States, page 468  
160 F. 2d 816 (C.C.A. 8, 1947)
- United States v. Walsh, trading as Kelp Laboratories, page 337  
331 U.S. 432 (1947)
- Manning v. United States, page 507  
161 F. 2d 827 (C.C.A. 5, 1947)
- Cook Chocolate Co. v. Miller et al., page 509  
72 F. Supp. 573 (D. of Col., 1947)
- United States v. Parfait Powder Puff Co., Inc., page 341  
163 F. 2d 1008 (C.C.A. 7, 1947), certiorari denied 332 U.S. 851 (1948)
- United States v. Kordel, page 343  
164 F. 2d 913 (C.C.A. 7, 1947)
- United States v. Roma Macaroni Factory et al., page 348  
75 F. Supp. 663 (N.D. Calif., 1947)
- Research Laboratories, Inc. v. Robert Hannegan, et al., page 514  
(D. Colo., 1947)
- United States v. Pinaud, Inc., page 526  
(S.D. N.Y., 1947) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Cosmetics (No. 152) Issued February 1949
- United States v. Crescent-Kelvan Company et al., page 359  
164 F. 2d 582 (C.C.A. 3, 1948)
- United States v. Dinshah P. Ghadiali and Dinshah Spectro-Chrome Institute, page 365  
165 F. 2d 957 (C.C.A. 3, 1948), certiorari denied 334 U.S. 821 (1948)



## SECTION 301 (a)—continued

- United States v. Bess J. Levine, trading as Miracle Food Co., page 367  
(E.D. Pa., 1948)
- Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States,  
page 370  
169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)
- United States v. Maryland Baking Co. and Sara Piem, an individual, page 379  
81 F. Supp. 560 (N.D. Ga., 1948)
- Kordel v. United States, page 382  
335 U.S. 345 (1948)
- United States v. Antonio Corrao, page 387  
(E.D. N.Y., 1948)
- United States v. Dr. Charles Kaadt and Dr. Peter S. Kaadt, page 388  
171 F. 2d 600 (C.A. 7, 1948)
- Lafayette M. Gray (also known as L. M. Gray), Appellant v. United States,  
page 537  
174 F. 2d 919 (C.A. 8, 1949)

## SECTION 301(b)

## 1938 Act Decisions

- United States v. Royal Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)
- United States v. Royal Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)
- United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)

## SECTION 301(c)

## Pertinent 1906 Act Decisions

- United States v. Great Atlantic & Pacific Tea Co.  
92 F. 2d 610 (C.C.A. 2, 1937), 113 A.L.R. 961

## / 1938 Act Decisions

- Sullivan v. United States, page 334  
161 F. 2d 629 (C.C.A. 5, 1947)

## Trade Correspondence

- TC-54, Feb. 12, 1940, page 590

## SECTION 301(g)

## 1938 Act Decisions

- Rubenstein v. United States, page 460  
153 F. 2d 127 (App. D.C., 1946)

## Trade Correspondence

- TC-250, April 25, 1940, page 666



**SECTION 301(h)****Regulations**

21 CFR, Cum. Supp., 2.4

**Pertinent 1906 Act Decisions**

United States v. Charles L. Heinle Specialty Co.  
175 Fed. 299 (E.D. Pa., 1910)

United States v. Mayfield et al.  
177 Fed. 765 (N.D. Ala., 1910)

Steinhardt Bros. & Co. v. United States  
191 Fed. 798 (C.C.A. 2, 1911)

Glaser, Kohn & Co. v. United States  
224 Fed. 84 (C.C.A. 7, 1915)

**1938 Act Decisions**

United States v. Buffalo Pharmacal Co., Inc., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)

United States v. Dotterweich, page 278  
320 U.S. 277 (1943)

Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)

United States v. Walsh, trading as Kelp Laboratories, page 337  
331 U.S. 432 (1947)

**Trade Correspondence**

TC-199, March 15, 1940, page 646

TC-200, March 15, 1940, page 646

TC-304, Aug. 20, 1940, page 688

TC-414, April 10, 1944, page 741

TC-428, May 5, 1945, page 746

**SECTION 301(k)****Pertinent 1906 Act Decisions**

McDermott v. State of Wisconsin  
228 U.S. 115 (1913)

**1938 Act Decisions**

United States v. Royal Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)

United States v. Royal Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)

United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)

United States v. Sullivan, page 319  
67 F. Supp. 192 (M.D. Ga., 1946)

Sullivan v. United States, page 334  
161 F. 2d 629 (C.C.A. 5, 1947)

United States v. Sullivan, page 350  
332 U.S. 689 (1948)

Kordel v. United States, page 382  
335 U.S. 345 (1948)

**Trade Correspondence**

TC- 54, Feb. 12, 1940, page 590

TC- 55, Feb. 12, 1940, page 591

TC-6-A, Feb. 14, 1946, page 752



## SECTION 302(a)

## 1938 Act Decisions

- United States v. Royal Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)
- United States v. Royal Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)
- United States v. 184 Barrels Dried Whole Eggs, page 59  
53 F. Supp. 652 (E.D. Wis., 1943)
- United States v. Swift & Co. et al., page 449  
53 F. Supp. 1018 (M.D. Ga., 1943)
- United States v. Sekov Corporation and Hazel Ruth Vokes (Sekov Studios),  
page 448  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 1001) Issued March 1945
- United States v. Lazere, page 451  
56 F. Supp. 730 (N.D. Iowa, 1944)
- United States v. Saunders Mills, Inc., Clarence M. Saunders, and Evelyn M. Crow,  
page 454  
(S.D. Ohio, 1944) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 8587) Issued July 1946
- United States v. G. Fred Obrecht, page 456  
(D. Md., 1945) Notices of Judgment Under the Federal Food, Drug, and  
Cosmetic Act, Foods (No. 8894) Issued February 1947
- Rubenstein v. United States, page 460  
153 F. 2d 127 (App. D.C., 1946)
- United States v. Paddock, page 462  
67 F. Supp. 819 (W.D. Mo., 1946)
- United States v. Paddock, page 463  
68 F. Supp. 407 (W.D. Mo., 1946)
- United States v. Dean Rubber Mfg. Co., et al., page 466  
71 F. Supp. 96 (W.D. Mo., 1946)
- United States v. Colgrove et al.  
83 F. Supp. 880 (S.D. Calif., 1947)
- Hygrade Food Products Corporation v. United States, page 468  
160 F. 2d 816 (C.C.A. 8, 1947)
- United States v. Dean Rubber Mfg. Co., et al., page 471  
72 F. Supp. 819 (W.D. Mo., 1947)
- United States v. Cowley Pharmaceuticals, Inc., page 473  
(D. Mass., 1948)
- United States v. Runkle Co., et al., page 475  
(N.D. Ohio, 1948)

## SECTION 302(b)

## 1938 Act Decisions

- United States v. Dean Rubber Mfg. Co., et al., page 466  
71 F. Supp. 96 (W.D. Mo., 1946)
- United States v. Dean Rubber Mfg. Co., et al., page 471  
72 F. Supp. 819 (W.D. Mo., 1947)
- Colgrove, etc. and Colusa Remedy Co. v. United States  
(C.A. 9, 1949)

## SECTION 303(a)

## Pertinent 1906 Act Decisions

- United States v. Schurman et al.  
177 Fed. 581 (W.D. Mich., 1910)
- United States v. Mayfield et al.  
177 Fed. 765 (N.D. Ala., 1910)



## SECTION 303 (a)—continued

- United States v. J. Lindsay Wells Co.  
186 Fed. 248 (W.D. Tenn., 1910)
- Frank et al v. United States  
192 Fed 864 (C.C.A. 6, 1911)
- Schraubstadter et al. v. United States  
199 Fed. 568 (C.C.A. 9, 1912)
- United States v. J. L. Hopkins & Co.  
199 Fed. 649 (E.D. N.Y., 1912)
- United States v. J. L. Hopkins & Co.  
228 Fed. 173 (S.D. N.Y., 1912)
- United States v. Wells  
225 Fed. 320 (W.D. Tenn., 1913)
- Weeks v. United States  
216 Fed. 292 (C.C.A. 2, 1914), certiorari denied 235 U.S. 697 (1914)
- United States v. Shallinger Produce Co.  
230 Fed. 290 (E.D. Wash., 1914)
- United States v. Rigney & Co.  
220 Fed 734 (E.D. N.Y., 1915)
- United States v. American Laboratories  
222 Fed. 104 (E.D. Pa., 1915)
- United States v. Simon et al.  
248 Fed. 980 (E.D. Pa., 1916)
- United States v. Bowers  
(E.D. Tenn., 1916). White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 763
- Simpson v. United States  
241 Fed 841 (C.C.A. 6, 1917), certiorari denied 245 U.S. 664 (1917)
- Abbott Bros. Co. v. United States  
242 Fed 751 (C.C.A. 7, 1917)
- United States v. Watson-Durand-Kasper Grocery Co.  
251 Fed. 310 (D. Kan., 1917)
- United States v. Direct Sales Co.  
252 Fed. 882 (W.D. N.Y., 1918)
- United States v. Eman Mfg. Co.  
271 Fed. 353 (D. Colo., 1920)
- United States v. Newton Tea & Spice Co.  
275 Fed. 394 (S.D. Ohio, 1920), affirmed 288 Fed. 475 (C.C.A. 6)
- Newton Tea & Spice Co. v. United States  
288 Fed. 475 (C.C.A. 6, 1923), affirming 275 Fed. 394 (S.D. Ohio)
- United States v. Alaska Consol. Canneries  
2 F. 2d 614 (W.D. Wash., 1924)
- Aycock v. O'Brien  
28 F. 2d 817 (C.C.A. 9, 1928)
- George A. Breon & Co., Inc. v. United States  
74 F. 2d 4 (C.C.A. 8, 1934)
- Strong, Cobb & Co., Inc. v. United States  
103 F. 2d 671 (C.C.A. 6, 1939)
- United States v. S. B. Penick & Co., et al.  
136 F. 2d 413 (C.C.A. 2, 1943)

## 1938 Act Decisions

- United States v. Commercial Creamery Co., page 257  
43 F. Supp. 714 (E.D. Wash., 1942)
- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- Empire Oil and Gas Corporation et al. v. United States, page 270  
136 F. 2d 868 (C.C.A. 9, 1943)
- United States v. Greenbaum, page 275  
138 F. 2d 437 (C.C.A. 3, 1943), 152 A.L.R. 751
- United States v. Dotterweich, page 278  
320 U.S. 277 (1943)
- United States v. Harold Hain (Hain Pure Food Co.) page 265  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)



## SECTION 303 (a)—continued

- United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)
- Joseph v. United States, page 303  
145 F. 2d 74 (C.C.A. 9, 1944), certiorari denied 323 U.S. 776 (1944)
- United States v. Douglas, page 318  
155 F. 2d 894 (C.C.A. 7, 1946)
- Manning v. United States, page 507  
161 F. 2d 827 (C.C.A. 5, 1947)
- United States v. Parfait Powder Puff Co., Inc., page 341  
163 F. 2d 1008 (C.C.A. 7, 1947), certiorari denied 332 U.S. 851 (1948)
- United States v. Kordel, page 343  
164 F. 2d 913 (C.C.A. 7, 1947)
- United States v. Roma Macaroni Factory et al., page 348  
75 F. Supp. 663 (N.D. Calif., 1947)
- Research Laboratories, Inc. v. Robert E. Hannegan, et al., page 514  
(D. Colo., 1947)
- United States v. Pinaud, Inc., page 526  
(S.D. N.Y., 1947) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Cosmetics (No. 152) Issued February 1949
- United States v. Crescent-Kelvan Company et al., page 359  
164 F. 2d 582 (C.C.A. 3, 1948)
- Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States, page 370  
169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)
- United States v. Bess J. Levine, trading as Miracle Food Co., page 367  
(E.D. Pa., 1948)
- United States v. Maryland Baking Company and Sara Piem, an individual, page 379  
81 F. Supp. 560 (N.D. Ga., 1948)
- Kordel v. United States, page 382  
335 U.S. 345 (1948)
- United States v. Antonio Corrao, page 387  
(E.D. N.Y., 1948)
- United States v. Dr. Charles Kaadt and Dr. Peter S. Kaadt, page 388  
171 F. 2d 600 (C.A. 7, 1948)
- Lafayette M. Gray, (Also Known as L. M. Gray), Appellant v. United States, page 537  
174 F. 2d 919 (C.A. 8, 1949)

## SECTION 303(b)

## Pertinent 1906 Act Decisions

- Alberty v. United States  
91 F. 2d 461 (C.C.A. 9, 1937)
- United States v. Dr. David Roberts Veterinary Co., Inc., et al.  
104 F. 2d 785 (C.C.A. 7, 1939)

## 1938 Act Decisions

- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Greenbaum, page 275  
138 F. 2d 437 (C.C.A. 3, 1943), 152 A.L.R. 731

## SECTION 303(c)

## Regulations

- 21 CFR, Cum. Supp., 2.5



## SECTION 303 (c)—continued

## Pertinent 1906 Act Decisions

- United States v. Charles L. Heinle Specialty Co.  
175 Fed. 299 (E.D. Pa., 1910)
- United States v. Mayfield et al.  
177 Fed. 765 (N.D. Ala., 1910)
- Steinhardt Bros. & Co. v. United States  
191 Fed. 798 (C.C.A. 2, 1911)
- Glaser, Kohn & Co. v. United States  
224 Fed. 84 (C.C.A. 7, 1915)

## 1938 Act Decisions

- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Dotterweich, page 278  
320 U.S. 277 (1943)
- United States v. Harold Hain (Hain Pure Food Co.), page 265  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 919) Issued October 1944
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)
- United States v. Crown Rubber Sundries Co. et al., page 330  
67 F. Supp. 92 (N.D. Ohio, 1946)
- United States v. Walsh, trading as Kelp Laboratories, page 337  
331 U.S. 432 (1947)
- United States v. Parfait Powder Puff Co., Inc., page 341  
163 F. 2d 1008 (C.C.A. 7, 1947), certiorari denied 332 U.S. 851 (1948)
- United States v. Bess J. Levine, trading as Miracle Food Company, page 367  
(E.D. Pa., 1948)

## Trade Correspondence

- |  |                                  |
|--|----------------------------------|
| TC- 12, Reprinted June 1941, page<br>568 | TC-304, Aug. 20, 1940, page 688  |
| TC-199, March 15, 1940, page 646         | TC-414, April 10, 1944, page 741 |
| TC-200, March 15, 1940, page 646         | TC-428, May 5, 1945, page 746    |

## Opinions of the Attorney General

- 26 Ops. Att'y Gen. 449, November 11, 1907

## SECTION 304(a)

## Pertinent 1906 Act Decisions

- United States v. Six Hundred and Fifty Cases of Tomato Catsup  
166 Fed. 773 (D. R.I., 1909)
- United States v. Sixty-Five Casks Liquid Extracts  
170 Fed. 449 (N.D. W.Va., 1909), affirmed 175 Fed. 1022 (C.C.A. 4)
- United States v. 779 Cases of Molasses  
174 Fed. 325 (C.C.A. 8, 1909)
- United States v. Nine Barrels of Olives  
179 Fed. 983 (E.D. Pa., 1910)
- United States v. Five Boxes of Asafoetida  
181 Fed. 561 (E.D. Pa., 1910)
- United States v. Forty-Six Packages and Bags of Sugar  
183 Fed. 642 (S.D. Ohio, 1910)
- United States v. Eight Packages and Casks of Drugs  
5 F. 2d 971 (S.D. Ohio, 1910)
- United States v. One Barrel Dessicated Egg Product  
(E.D. Pa., 1910) White and Gates, "Decisions of Courts in Cases Arising  
Under the Federal Food and Drugs Act," p. 99
- United States v. Two Barrels of Dessicated Eggs  
185 Fed. 302 (D. Minn., 1911)



## SECTION 304 (a)—continued

- United States v. George Spraul & Co.  
185 Fed. 405 (C.C.A. 6, 1911)
- Hipolite Egg Company v. United States  
220 U.S. 45 (1911)
- United States v. Twenty Cases of Grape Juice  
189 Fed. 331 (C.C.A. 2, 1911)
- United States v. 300 Cans of Frozen Eggs  
189 Fed. 351 (C.C.A. 2, 1911)
- United States v. Certain Cans of Syrup  
192 Fed. 79 (E.D. Pa., 1911)
- United States v. Seventy-Five Barrels of Vinegar  
192 Fed. 350 (N.D. Iowa, 1911)
- Four Hundred and Forty-Three Cans of Frozen Egg Product v. United States  
226 U.S. 172 (1912)
- United States v. Hudson Mfg. Co., et al.  
200 Fed. 956 (C.C.A. 5, 1912)
- McDermott v. State of Wisconsin  
228 U.S. 115 (1913)
- United States v. Thirteen Crates of Frozen Eggs  
208 Fed. 950 (S.D. N.Y., 1913), affirmed 215 Fed. 584 (C.C.A. 2)
- United States v. Thirty-Six Bottles of London Dry Gin et al.  
210 Fed. 271 (C.C.A. 3, 1914)
- United States v. Thirteen Crates of Frozen Eggs  
215 Fed. 584 (C.C.A. 2, 1914)
- United States v. 267 Boxes of Macaroni  
225 Fed. 79 (W.D. Pa., 1915)
- United States v. 60 Barrels of Wine  
225 Fed. 846 (W.D. Mo., 1915)
- United States v. 426 Bags of Economy Special Hog Feed  
276 Fed. 34 (W.D. Mich., 1921)
- A. O. Andersen & Co. v. United States  
284 Fed. 542 (C.C.A. 9, 1922)
- United States v. Blazek  
(D. N. Dak., 1923) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1074
- United States v. Two Hundred Cases, More or Less, of Canned Salmon  
289 Fed. 157 (S.D. Tex., 1923)
- United States v. 496 Cases of Canned Salmon  
(E.D. Mo., 1924) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1099
- United States v. 1,600 Cases of Canned Salmon  
(D. Ore., 1924) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1105
- United States v. 95 Barrels, More or Less, Alleged Apple Cider Vinegar  
265 U.S. 438 (1924)
- Goodwin et al. v. United States  
2 F. 2d 200 (C.C.A. 6, 1924)
- United States v. Eighteen Cases of Tuna Fish  
5 F. 2d 979 (W.D. Va., 1925)
- United States v. 2,205 Cases of Canned Salmon  
(W.D. Tex., 1925) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1133
- United States v. Capon Water Co.  
30 F. 2d 300 (E.D. Pa., 1929)
- United States v. B. & M. External Remedy  
36 F. 2d 53 (S.D. N.Y., 1929)
- United States v. 23 7/12 Dozen Bottles \* \* \* "Lee's Save the Baby"  
44 F. 2d 831 (D. Conn., 1930)
- United States v. 94 Dozen \* \* \* Bottles Capon Springs Water  
48 F. 2d 378 (E.D. Pa., 1929, 1930), affirmed 51 F. 2d 913 (C.C.A. 3)
- United States v. Ten Cases \* \* \* Bred Spred, etc.  
49 F. 2d 87 (C.C.A. 8, 1931)
- National Remedy Co. v. Hyde  
50 F. 2d 1066 (App. D.C., 1931)
- United States v. 94 Dozen \* \* \* Bottles Capon Springs Water  
51 F. 2d 913 (C.C.A. 3, 1931)



## SECTION 304 (a)—continued

- United States v. W. T. Rawleigh Co.  
57 F. 2d 505 (C.C.A. 10, 1932)
- United States v. 800 Sacks Barley Mixed Oats  
64 F. 2d 678 (C.C.A. 5, 1933)
- United States v. 1,443 Cases, More or Less, Canned Salmon, etc.  
7 F. Supp. 77 (W.D. Wash., 1934)
- United States v. 462 Bags of Flour  
8 F. Supp. 79 (W.D. La., 1934)
- United States v. 5 One-Pint Bottles \* \* \* Elixir Terpin Hydrate and Codeine  
9 F. Supp. 990 (S.D. N.Y., 1934)
- United States v. 52 One-Gallon Cans, More or Less, of Salad Oil  
16 F. Supp. 385 (D. Conn., 1935)
- Van Camp Sea Food Co., Inc. v. United States  
82 F. 2d 365 (C.C.A. 3, 1936)
- United States v. 119 Packages \* \* \* Z-G Herbs  
15 F. Supp. 327 (S.D. N.Y., 1936)
- United States v. 397 Cases, etc., of Salad Oil  
16 F. Supp. 387 (D. N.J., 1936)
- United States v. Washington Dehydrated Food Co.  
89 F. 2d 606 (C.C.A. 8, 1937)
- United States v. 492 Cases \* \* \* Orange Juice  
20 F. Supp. 520 (E.D. La., 1937), affirmed 96 F. 2d 972 (C.C.A. 5)
- United States v. 133 Cases of Tomato Paste  
22 F. Supp. 515 (E.D. Pa., 1938)
- United States v. 48 Dozen Packages \* \* \* Gauze Bandage  
94 F. 2d 641 (C.C.A. 2, 1938)
- United States v. Nesbitt Fruit Products, Inc.  
96 F. 2d 972 (C.C.A. 5, 1938), affirming 20 F. Supp. 520 (E.D. La.)
- United States v. One Can of Kololiva  
24 F. Supp. 110 (D. Mass., 1938)
- United States v. 52 Drums Maple Syrup  
110 F. 2d 914 (C.C.A. 2, 1940)
- Sinclair G. Stanley v. United States  
111 F. 2d 898 (C.C.A. 6, 1940)
- United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
32 F. Supp. 958 (S.D. N.Y., 1940)
- George H. Lee Co. v. Federal Trade Commission  
113 F. 2d 583 (C.C.A. 8, 1940) [with respect to *res judicata*]

## 1938 Act Decisions

- United States v. 376 Dozen Small Size, etc., Emerson's Bromo Seltzer, page 1  
(S.D. N.Y., 1939) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 81) Issued May 1940 [Removal]
- United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942
- United States v. 6 Devices, "Electreat Mechanical Heart," page 5  
38 F. Supp. 236 (W.D. Mo., 1941)
- United States v. 11¼ Dozen Packages \* \* \* "Mrs. Moffat's Shoo Fly Powders for Drunkenness," page 8  
40 F. Supp. 208 (W.D. N.Y., 1941)
- United States v. Fifteen Cartons \* \* \* Sekov Reducer, page 12  
(S.D. Tex., 1941) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1002) Issued March 1945 [Removal]
- United States v. Research Laboratories, Inc., page 15  
126 F. 2d 42 (C.C.A. 9, 1942), certiorari denied 317 U.S. 656 (1942)
- United States v. 1232 Cases \* \* \* American Beauty Brand Oysters, page 18  
43 F. Supp. 749 (W.D. Mo., 1942)
- United States v. 29 Bottles \* \* \* "Ocean-Lax," etc., page 21  
44 F. Supp. 317 (E.D. Pa., 1942)
- United States v. Fifteen Cartons \* \* \* Sekov Reducer, page 22  
45 F. Supp. 52 (S.D. Tex., 1942)



## SECTION 304 (a)—continued

- United States v. 45 $\frac{2}{3}$  Dozen Packages \* \* \* "U-X Improved Shaving Medium,"  
page 25  
46 F. Supp. 112 (S.D. N.Y., 1942)
- United States v. 893 One-Gallon Cans \* \* \* "Brown's Inhalant," page 26  
45 F. Supp. 467 (D. Del., 1942)
- United States v. 1,375 Cases of Tomato Paste, page 13  
(D. Conn., 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 3761) Issued May 1943
- United States v. 108 Boxes of Cheddar Cheese, page 33  
(S.D. Iowa, 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 5478) Issued January 1945
- United States v. 998 Cases of Tomato Puree, page 28  
(W.D. Mich., 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7850) Issued January 1946
- United States v. 667 Cases of Canned Herring Roe, page 30  
(D. Md., 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 8917) Issued February 1947
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. 935 Cases \* \* \* Tomato Puree, page 44  
136 F. 2d 523 (C.C.A. 6, 1943), certiorari denied 320 U.S. 778 (1943)
- Helco Products Co., Inc. v. McNutt, et al, page 477  
137 F. 2d 681 (App. D.C., 1943), 149 A.L.R. 345
- United States of America v. 284 Barrels of Dried Eggs, etc., page 48  
52 F. Supp. 661 (W.D. Tenn., 1943)
- United States v. 143 Packages \* \* \* Nue-Ovo, page 50  
51 F. Supp. 1 (W.D. Wash., 1943)
- Sekov Corporation v. United States, page 53  
139 F. 2d 197 (C.C.A. 5, 1943)
- United States v. 149 Gift Packages, page 54  
52 F. Supp. 993 (E.D. N.Y., 1943)
- United States v. 55 Cases Popped Corn et al., page 56  
62 F. Supp. 843 (D. Idaho, 1943)
- In re United States, page 480  
140 F. 2d 19 (C.C.A. 5, 1943)
- United States v. 184 Barrels Dried Whole Eggs, page 59  
53 F. Supp. 652 (E.D. Wis., 1943)
- United States v. 650 Bags of Roasted Malted Cereal et al., page 51  
(W.D. Mo., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 6403) Issued June 1945
- United States v. 379 Bottles \* \* \* of Grayvita, page 58  
(N.D. Ill., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7905) Issued January 1946 [Removal]
- United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- Fresh Grown Preserves Corporation et al. v. United States, page 490  
144 F. 2d 136 (C.C.A. 4, 1944)
- United States v. 2 Bags \* \* \* Poppy Seeds, page 78  
54 F. Supp. 706 (N.D. Ohio, 1944)
- United States v. Willard Tablet Co., page 80  
141 F. 2d 141 (C.C.A. 7, 1944)
- United States v. 75 Cases \* \* \* Peanut Butter, etc., page 82  
54 F. Supp. 641 (D. Md., 1944)
- United States v. 720 Bottles \* \* \* Plantation Pure Vanilla Extract, etc., page  
482  
3 F.R.D. 466 (E.D. N.Y., 1944)
- United States v. Seven Barrels, etc., "Spray Dried Whole Egg," page 85  
141 F. 2d 767 (C.C.A. 7, 1944)
- United States v. 50 $\frac{3}{4}$  Dozen Bottles, More or Less, of "Sulfa-Seb" et al., page 94  
54 F. Supp. 759 (W.D. Mo., 1944)
- United States v. 306 Cases \* \* \* "Sandford Tomato Catsup with Preservative,"  
page 115  
55 F. Supp. 725 (E.D. N.Y., 1944)
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets et al., page 107  
142 F. 2d 107 (C.C.A. 7, 1944), certiorari denied 323 U.S. 731 (1944)



## SECTION 304 (a)—continued

- Arner Co., Inc. et al. v. United States, page 99  
 142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)
- United States v. 1851 Cartons \* \* \* Whiting Frosted Fish, page 110  
 55 F. Supp. 343 (D. Colo., 1944)
- United States v. Six Dozen Bottles \* \* \* "Dr. Peter's Kuriko," page 118  
 55 F. Supp. 458 (E.D. Wis., 1944)
- Fresh Grown Preserve Corporation v. United States, page 484  
 143 F. 2d 191 (C.C.A. 6, 1944)
- United States v. 74 Cases \* \* \* "C.C. Brand Oysters," page 119  
 55 F. Supp. 745 (W.D. S.C., 1944)
- Fred B. Collier, etc. v. Paul V. McNutt, Federal Security Administrator, et al.,  
 page 493  
 (D. of Col., 1944) Notices of Judgment Under the Federal Food, Drug,  
 and Cosmetic Act, Drugs and Devices (No. 2140) Issued April 1948
- United States v. 1 Dozen Bottles \* \* \* "Bonquet Tablets," page 122  
 146 F. 2d 361 (C.C.A. 4, 1944)
- United States v. 75 Cases \* \* \* Peanut Butter, etc., page 126  
 146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S. 856 (1945)
- United States v. 70½ Dozen Bottles \* \* \* of "666," page 89  
 (M.D. Ga., 1944) Notices of Judgment Under the Federal Food, Drug,  
 and Cosmetic Act, Drugs and Devices (No. 1231) Issued June 1945
- United States v. 2,640 Cases of Dried Prunes, page 122  
 (W.D. N.C., 1944) Notices of Judgment Under the Federal Food, Drug,  
 and Cosmetic Act, Foods (No. 7277) Issued September 1945 [Removal]
- United States v. 1851 Cartons \* \* \* Whiting Frosted Fish et al., page 134  
 146 F. 2d 760 (C.C.A. 10, 1945)
- C. C. Co. v. United States, page 129  
 147 F. 2d 820 (C.C.A. 5, 1945)
- United States v. Two Bags \* \* \* Poppy Seeds, etc., page 135  
 147 F. 2d 123 (C.C.A. 6, 1945)
- Libby, McNeill & Libby v. United States, page 145  
 148 F. 2d 71 (C.C.A. 2, 1945)
- United States v. 600 Units \* \* \* "Nue-Ovo," etc., page 154  
 60 F. Supp. 144 (W.D. Mo., 1945)
- United States v. 24 Cans, etc., Butter et al., page 156  
 148 F. 2d 365 (C.C.A. 5, 1945), certiorari denied 326 U.S. 752 (1945)
- United States v. 26 Dozen Bottles, etc., "Wheatamin Brand Cevigards," page 154  
 60 F. Supp. 626 (W.D. Mich., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
 page 149  
 59 F. Supp. 284 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
 page 159  
 61 F. Supp. 847 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
 page 161  
 61 F. Supp. 850 (W.D. La., 1945)
- United States v. Five Cases \* \* \* "Capon Springs Water," page 141  
 62 F. Supp. 736 (S.D. N.Y., 1945)
- United States v. 254 Cases \* \* \* "Baby Brand Tomato Sauce," etc., page 162  
 63 F. Supp. 916 (E.D. Ark., 1945)
- United States v. 738 Cases \* \* \* "Jiffy-Lou Vanilla Flavor Pudding," page 171  
 71 F. Supp. 279 (D. Ariz., 1946)
- United States v. 43½ Gross \* \* \* "Xcello's Rubber Prophylactics," et al.,  
 page 173  
 65 F. Supp. 534 (D. Minn., 1946)
- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
 65 F. Supp. 503 (N.D. Ohio, 1946)
- United States v. One Article of Device Labeled Spectro-Chrome et al., page 207  
 66 F. Supp. 754 (D. Ore., 1946)
- Byrd v. United States, page 177  
 154 F. 2d 62 (C.C.A. 5, 1946)
- United States v. 14 Cartons \* \* \* "Ayds Candy \* \* \*," page 182  
 (E.D. Mo., 1946)



## SECTION 304 (a)—continued

- United States v. Five Cases \* \* \* "Capon Springs Water," page 187  
156 F. 2d 493 (C.C.A. 2, 1946)
- United States v. 88 Cases \* \* \* "Bireley's Orange Beverage," page 501  
5 F.R.D. 503 (D. N.J., 1946)
- United States v. Phelps Dodge Mercantile Co., page 189  
157 F. 2d 453 (C.C.A. 9, 1946), certiorari denied 330 U.S. 818 (1947)
- United States v. 3 Unlabeled 25-Pound Bags Dried Mushrooms et al., page 191  
157 F. 2d 722 (C.C.A. 7, 1946)
- United States v. Cataldo, page 193  
157 F. 2d 802 (C.C.A. 1, 1946)
- United States v. 1322 Cans \* \* \* Black Raspberry Puree, page 195  
68 F. Supp. 881 (N.D. Ohio, 1946)
- United States v. 300 Cans, etc., of Black Raspberries, et al., page 505  
7 F.R.D. 36 (N.D. Ohio, 1946)
- United States v. 12 Bottles of Esterex, page 523  
(E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949
- United States v. Six Dozen Bottles \* \* \* "Dr. Peter's Kuriko," page 197  
158 F. 2d 667 (C.C.A. 7, 1947)
- United States v. One Device, etc., "Tox Eliminator," etc., page 199  
160 F. 2d 194 (C.C.A. 10, 1947)
- Gellman v. United States, page 205  
159 F. 2d 881 (C.C.A. 8, 1947)
- United States v. Olsen, page 210  
161 F. 2d 669 (C.C.A. 9, 1947), certiorari denied 332 U.S. 768 (1947)
- Cook Chocolate Co. v. Miller et al., page 509  
72 F. Supp. 573 (D. of Col., 1947)
- United States v. 150 Packages, etc., Labeled In Part Bush Mulso Tablets et al.  
83 F. Supp. 875 (E.D. Mo., 1947)
- United States v. 20 Cases, etc., of Jell-O Vanilla Flavor Pudding, page 212  
77 F. Supp. 231 (S.D. N.Y., 1947)
- United States v. 74 Cases \* \* \* Plum Jelly et al., page 511  
73 F. Supp. 1009 (D. Minn., 1947)
- United States v. 215 Cases \* \* \* "Michigan Brand Grade A Tomato Catsup \* \* \*," page 513  
(E.D. N.Y., 1947)
- Urbeteit, etc. v. United States, page 212  
164 F. 2d 245 (C.C.A. 5, 1947)
- United States v. 36 Drums of Pop'N Oil, page 215  
164 F. 2d 250 (C.C.A. 5, 1947)
- United States v. 9 Bottles \* \* \* "Colusa Natural Oil," etc., page 218  
78 F. Supp. 721 (N.D. Iowa, 1947)
- Research Laboratories, Inc. v. Robert E. Hannegan, et al., page 514  
(D. Colo., 1947)
- 338 Cartons, More or Less, of Butter et al. v. United States, page 222  
165 F. 2d 728 (C.C.A. 4, 1947)
- Salamonie Packing Company v. United States, page 225  
165 F. 2d 205 (C.C.A. 8, 1948), certiorari denied 333 U.S. 863 (1948)
- United States v. One Article of Device Labeled Spectro-Chrome, page 226  
77 F. Supp. 50 (D. Ore., 1948)
- Research Laboratories, Inc. v. United States, page 227  
167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948)
- 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
168 F. 2d 361 (C.C.A. 6, 1948)
- United States v. Kent Food Corp. and Clark-Iger Food Products Co., Inc., page 242  
168 F. 2d 632 (C.C.A. 2, 1948), certiorari denied 335 U.S. 885 (1948)
- United States v. 99 Cases \* \* \* Peach Fountain Fruit, etc., page 245  
(E.D. Tenn., 1948)
- Smith v. Great Atlantic & Pacific Tea Co., page 514  
170 F. 2d 474 (C.A. 8, 1948)
- United States v. 116 Boxes \* \* \* "Arden Assorted Candy Drops," etc., page 247  
80 F. Supp. 911 (D. Mass., 1948)
- United States v. Urbeteit, page 249  
335 U.S. 355 (1948)
- United States v. 5 Cases \* \* \* "Figlia Mia Brand \* \* \*," et al., page 521  
(D. Conn., 1949)



## SECTION 304 (a)—continued

- United States v. Two Articles of Device \* \* \* "Tox Eliminator," etc., page 529  
(E.D. Okla., 1949)
- United States v. Various Quantities of \* \* \* "Instant Alberty Food \* \* \*," etc.,  
page 533  
83 F. Supp. 882 (D. of Col., 1949)
- United States v. 104 Cases \* \* \* "Colorado Gold Brand Creamery Butter \* \* \*,"  
page 526  
(S.D. Calif., 1949)
- United States v. Urbeteit, etc., page 560  
336 U.S. 804 (1949)
- United States v. Four Devices, Labeled in Part "Color-Therm" etc., and Franklin  
D. Lee  
(C.A. 10, 1949)
- Colusa Remedy Co. v. United States  
(C.A. 8, 1949)
- Urbeteit v. United States  
(C.A. 5, 1949)

## Of Incidental Interest

- Great Atlantic & Pacific Tea Co. v. Smith  
75 F. Supp. 156 (W.D. Ark., 1948), affirmed 170 F. 2d 474 (C.A. 8)
- Miles Laboratories, Inc. v. Federal Trade Commission  
140 F. 2d 683 (App. D.C., 1944), certiorari denied 322 U.S. 752 (1944)

Pertinent Federal Trade Commission Act Decisions  
With Respect to Res Judicata

- George H. Lee Company v. Federal Trade Commission  
113 F. 2d 583 (C.C.A. 8, 1940)
- Raladam Company v. Federal Trade Commission  
123 F. 2d 34 (C.C.A. 6, 1941)
- Federal Trade Commission v. Raladam Co.  
316 U.S. 149 (1942)

## SECTION 304(b)

## Pertinent 1906 Act Decisions

- United States v. 779 Cases of Molasses  
174 Fed. 325 (C.C.A. 8, 1909)
- United States v. George Spraul & Co.  
185 Fed. 405 (C.C.A. 6, 1911)
- Goode v. United States  
44 App. D.C. 162 (1915)
- Goodwin et al. v. United States  
2 F. 2d 200 (C.C.A. 6, 1924)
- United States v. Eighteen Cases of Tuna Fish  
5 F. 2d 979 (W.D. Va., 1925)
- United States v. Ten Cases \* \* \* Bred Spred, etc.  
49 F. 2d 87 (C.C.A. 8, 1931)
- United States v. French Sardine Co., Inc.  
80 F. 2d 325 (C.C.A. 9, 1935)
- United States v. 397 Cases, etc., of Salad Oil  
16 F. Supp. 387 (D. N.J., 1936)
- United States v. Lee  
107 F. 2d 522 (C.C.A. 7, 1939), certiorari denied 309 U.S. 659 (1940)
- United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
32 F. Supp. 958 (S.D. N.Y., 1940)

## 1938 Act Decisions

- United States v. 376 Dozen Small Size, etc., Emerson's Bromo Seltzer, page 1  
(S.D. N.Y., 1939) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 81) Issued May 1940
- United States v. 15 Cartons \* \* \* Sekov Reducer, page 12  
(S.D. Tex., 1941) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 1002) Issued March 1945



## SECTION 304 (b)—continued

- United States v. Research Laboratories, Inc., page 15  
126 F. 2d 42 (C.C.A. 9, 1942), certiorari denied 317 U.S. 656 (1942)
- United States v. 29 Bottles \* \* \* "Ocean-Lax," etc., page 21  
44 F. Supp. 317 (E.D. Pa., 1942)
- United States v. 45 $\frac{2}{3}$  Dozen Packages \* \* \* "U-X Improved Shaving Medium,"  
page 25  
46 F. Supp. 112 (S.D. N.Y., 1942)
- United States v. 108 Boxes of Cheddar Cheese, page 33  
(S.D. Iowa, 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 5478) Issued January 1945
- United States v. 998 Cases of Tomato Puree, page 28  
(W.D. Mich., 1942) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7850) Issued January 1946
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. 935 Cases \* \* \* Tomato Puree, page 44  
136 F. 2d 523 (C.C.A. 6, 1943), certiorari denied 320 U.S. 778 (1943)
- Helco Products Co., Inc. v. McNutt, et al., page 477  
137 F. 2d 681 (App. D.C., 1943)
- Sekov Corporation v. United States, page 53  
139 F. 2d 197 (C.C.A. 5, 1943)
- United States v. 149 Gift Packages, page 54  
52 F. Supp. 993 (E.D. N.Y., 1943)
- United States v. 184 Barrels Dried Whole Eggs, page 59  
53 F. Supp. 652 (E.D. Wis., 1943)
- United States v. 379 Bottles \* \* \* of Grayvita, page 58  
(N.D. Ill., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7905) Issued January 1946
- United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- United States v. 75 Cases \* \* \* Peanut Butter, etc., page 82  
54 F. Supp. 641 (D. Md., 1944)
- United States v. 720 Bottles \* \* \* Plantation Pure Vanilla Extract, etc., page 482  
3 F.R.D. 466 (E.D. N.Y., 1944)
- Fresh Grown Preserve Corporation v. United States, page 484  
143 F. 2d 191 (C.C.A. 6, 1944)
- United States v. Six Dozen Bottles \* \* \* "Dr. Peter's Kuriko," page 118  
55 F. Supp. 458 (E.D. Wis., 1944)
- United States v. 74 Cases \* \* \* "C. C. Brand Oysters," page 119  
55 F. Supp. 745 (W.D. S.C., 1944)
- United States v. 75 Cases \* \* \* Peanut Butter, page 126  
146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S. 856 (1945)
- United States v. 2,640 Cases of Dried Prunes, page 122  
(W.D. N.C., 1944) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 7277) Issued September 1945
- C. C. Co. v. United States, page 129  
147 F. 2d 820 (C.C.A. 5, 1945)
- United States v. 600 Units \* \* \* "Nue-Ovo," etc., page 154  
60 F. Supp. 144 (W.D. Mo., 1945)
- United States v. 26 Dozen Bottles, etc., "Wheatamin Brand Cevigards," page 154  
60 F. Supp. 626 (W.D. Mich., 1945)
- United States v. 88 Cases \* \* \* "Bireley's Orange Beverage," page 501  
5 F.R.D. 503 (D. N.J., 1946)
- United States v. Cataldo, page 193  
157 F. 2d 802 (C.C.A. 1, 1946)
- United States v. 300 Cans, etc., of Black Raspberries et al., page 505  
7 F.R.D. 36 (N.D. Ohio, 1946)
- United States v. 20 Cases, etc., of Jello Vanilla Flavor Pudding, page 212  
77 F. Supp. 231 (S.D. N.Y., 1947)
- United States v. 74 Cases \* \* \* Plum Jelly et al., page 511  
73 F. Supp. 1009 (D. Minn., 1947)
- United States v. 5 Cases \* \* \* "Figlia Mia Brand \* \* \* " et al., page 521  
(D. Conn., 1949)
- Colusa Remedy Co. v. United States  
(C.A. 8, 1949)



## SECTION 304(c)

## 1938 Act Decisions

- United States v. 108 Boxes of Cheddar Cheese, page 33  
(S.D. Iowa, 1942), Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 5478) Issued January 1945
- United States v. 720 Bottles \* \* \* Plantation Pure Vanilla Extract, etc., page 482  
3 F.R.D. 466 (E.D. N.Y., 1944)
- United States v. 43½ Gross \* \* \* "Xcello's Rubber Prophylactics," et al., page  
173  
65 F. Supp. 534 (D. Minn., 1946)
- United States v. 88 Cases \* \* \* "Bireley's Orange Beverage," page 501  
5 F.R.D. 503 (D. N.J., 1946)
- United States v. 300 Cans, etc., of Black Raspberries et al., page 505  
7 F.R.D. 36 (N.D. Ohio, 1946)
- United States v. 5 Cases \* \* \* "Figlia Mia Brand \* \* \* " et al., page 521  
(D. Conn., 1949)

## SECTION 304(d)

## Pertinent 1906 Act Decisions

- United States v. 100 Cases of Tepee Apples et al.  
179 Fed. 985 (W.D. Mo., 1908)
- United States v. Nine Barrels of Butter  
241 Fed. 499 (S.D. N.Y., 1917)
- United States v. Six Barrels of Ground Pepper  
253 Fed. 199 (S.D. N.Y., 1917)
- United States v. Two Cans of Oil of Sweet Birch and Three Cans of Oil of  
Gaultheria  
268 Fed. 866 (S.D. N.Y., 1920)
- A. O. Andersen & Co. v. United States  
284 Fed. 542 (C.C.A. 9, 1922)
- United States v. Two Hundred Cases, More or Less, of Canned Salmon  
289 Fed. 157 (S.D. Tex., 1923)
- United States v. 1,443 Cases, More or Less, Canned Salmon, etc.  
7 F. Supp. 77 (W.D. Wash., 1934)
- United States v. 462 Bags of Flour  
8 F. Supp. 79 (W.D. La., 1934)
- United States v. 397 Cases, etc., of Salad Oil  
16 F. Supp. 387 (D. N.J., 1936)

## 1938 Act Decisions

- United States v. 893 One-Gallon Cans \* \* \* "Brown's Inhalant," page 26  
45 F. Supp. 467 (D. Del., 1942)
- United States v. 143 Packages \* \* \* Nue-Ovo, page 50  
51 F. Supp. 1 (W.D. Wash., 1943)
- In re United States, page 480  
140 F. 2d 19 (C.C.A. 5, 1943)
- Fresh Grown Preserve Corporation v. United States, page 484  
143 F. 2d 191 (C.C.A. 6, 1944)
- Fresh Grown Preserves Corporation et al. v. United States, page 490  
144 F. 2d 136 (C.C.A. 4, 1944)
- United States v. 254 Cases \* \* \* "Baby Brand Tomato Sauce," etc., page 162  
63 F. Supp. 916 (E.D. Ark., 1945)
- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
65 F. Supp. 503 (N.D. Ohio, 1946)
- United States v. 43½ Gross \* \* \* "Xcello's Rubber Prophylactics," et al.,  
page 173  
65 F. Supp. 534 (D. Minn., 1946)
- United States v. 1322 Cans \* \* \* Black Raspberry Puree, page 195  
68 F. Supp. 881 (N.D. Ohio, 1946)
- Gellman v. United States, page 205  
159 F. 2d 881 (C.C.A. 8, 1947)
- United States v. 215 Cases \* \* \* "Michigan Brand Grade A Tomato Catsup  
\* \* \*," page 513  
(E.D. N.Y., 1947)



## SECTION 304 (d)—continued

- 338 Cartons, More or Less, of Butter et al. v. United States, page 222  
 165 F. 2d 728 (C.C.A. 4, 1947)
- United States v. 150 Packages, etc., Labeled in Part Bush Mulso Tablets et al.  
 83 F. Supp. 875 (E.D. Mo., 1947)
- Research Laboratories, Inc. v. United States, page 227  
 167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948)
- United States v. Kent Food Corporation and Clark-Iger Food Products Co., Inc.,  
 page 242  
 168 F. 2d 632 (C.C.A. 2, 1948), certiorari denied 335 U.S. 885 (1948)
- United States v. 99 Cases \* \* \* Peach Fountain Fruit, etc., page 245  
 (E.D. Tenn., 1948)
- Stinson Canning Co. et al. v. United States, page 518  
 170 F. 2d 764 (C.A. 4, 1948)
- Colusa Remedy Co. v. United States  
 (C.A. 8, 1949)

## SECTION 304(e)

## Pertinent 1906 Act Decisions

- Charles v. United States  
 183 Fed. 566 (C.C.A. 5, 1910)
- United States v. 1,590 Cases of Tomato Pulp  
 255 Fed. 288 (E.D. Pa., 1919)
- United States v. French Sardine Co., Inc.  
 80 F. 2d 325 (C.C.A. 9, 1935)
- United States v. One Can of Kololiva  
 24 F. Supp. 110 (D. Mass., 1938)
- United States v. Lee  
 107 F. 2d 522 (C.C.A. 7, 1939), certiorari denied 309 U.S. 659 (1940)
- United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
 32 F. Supp. 958 (S.D. N.Y., 1940)

## SECTION 305

## Regulations

21 CFR, Cum. Supp., 2.6

## Pertinent 1906 Act Decisions

- United States v. Nine Barrels of Olives  
 179 Fed. 983 (E.D. Pa., 1910)
- United States v. Morgan  
 222 U.S. 274 (1911)
- United States v. 94 Dozen \* \* \* Bottles Capon Springs Water  
 51 F. 2d 913 (C.C.A. 3, 1931)
- United States v. King & Howe, Inc., et al.  
 78 F. 2d 693 (C.C.A. 2, 1935)

## 1938 Act Decisions

- United States v. Commercial Creamery Co., page 257  
 43 F. Supp. 714 (E.D. Wash., 1942)
- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
 131 F. 2d 500 (C.C.A. 2, 1942)
- Helco Products Co., Inc. v. McNutt et al., page 477  
 137 F. 2d 681 (App. D.C., 1943)
- United States v. Greenbaum, page 275  
 138 F. 2d 437 (C.C.A. 3, 1943), 152 A.L.R. 751
- United States v. Dotterweich, page 278  
 320 U.S. 277 (1943)
- Cook Chocolate Co. v. Miller et al., page 509  
 72 F. Supp. 573 (D. of Col., 1947)



## SECTION 306

## 1938 Act Decisions

- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
65 F. Supp. 503 (N.D. Ohio, 1946)  
United States v. Sullivan, page 350  
332 U.S. 689 (1948)
- 

## SECTION 307

## 1938 Act Decisions

- Helco Products Co., Inc. v. McNutt, et al., page 477  
137 F. 2d 681 (App. D.C., 1943)  
Cook Chocolate Co. v. Miller et al., page 509  
72 F. Supp 573 (D. of Col., 1947)
- 

## SECTION 401

## Regulations

- 21 CFR, Cum. Supp., 2.701 *et seq.*, 5 F.R. 2379 (Rules of Practice for Hearings)  
21 CFR, Cum. Supp., Sec. 10.0 *et seq.*, 4 F.R. 3320 (General Regulations, Definitions, and Standards for Food)  
21 CFR, 1943 Supp., Sec. 10.0, 8 F.R. 9937  
13 F.R. 7327  
Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 2, Rev. 1,  
Issued January 1949  
13 F.R. 6377 *et seq.* (Republishing all currently effective definitions and standards for food, for the purpose of compiling the regulations and amendments without change); 13 F.R. 6969; 14 F.R. 2411; 14 F.R. 2544

## Pertinent 1906 Act Decisions

- Morgan et al. v. Nolan, United States Att'y.  
3 F. Supp. 143 (S.D. Ind., 1933)  
Nolan, United States Att'y. v. Morgan et al.  
69 F. 2d 471 (C.C.A. 7, 1934)

## 1938 Act Decisions

- A. E. Staley Mfg. Co. v. Secretary of Agriculture et al., page 395  
120 F. 2d 258 (C.C.A. 7, 1941)  
Twin City Milk Producers Ass'n. et al. v. McNutt et al., page 398  
122 F. 2d 564 (C.C.A. 8, 1941)  
Twin City Milk Producers Ass'n. v. McNutt et al., page 403  
123 F. 2d 396 (C.C.A. 8, 1941)  
Quaker Oats Co. v. Federal Security Administrator, page 405  
129 F. 2d 76 (C.C.A. 7, 1942)  
Land O'Lakes Creameries, Inc., et al. v. McNutt et al., page 412  
132 F. 2d 653 (C.C.A. 8, 1943)  
Federal Security Administrator v. Quaker Oats Co., page 419  
318 U.S. 218 (1943)  
Columbia Cheese Co. et al. v. McNutt, page 426  
137 F. 2d 576 (C.C.A. 2, 1943); certiorari denied 321 U.S. 777 (1944)  
United States Cane Sugar Refiners' Ass'n. et al. v. McNutt, page 431  
138 F. 2d 116 (C.C.A. 2, 1943)  
United States v. 306 Cases \* \* \* "Sandford Tomato Catsup with Preservative,"  
page 115  
55 F. Supp. 725 (E.D. N.Y., 1944)  
United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)



## SECTION 401—continued

- Libby, McNeill & Libby v. United States, page 145  
 148 F. 2d 71 (C.C. A. 2, 1945)  
 American Lecithin Co., Inc. v. McNutt, page 438  
 155 F. 2d 784 (C.C.A. 2, 1946), certiorari denied 329 U.S. 763 (1946)  
 United States v. 36 Drums of Pop'N Oil, page 215  
 164 F. 2d 250 (C.C.A. 5, 1947)  
 Willapoint Oysters, Inc. v. Ewing et al., page 543  
 174 F. 2d 676 (C.A. 9, 1949)  
 United States v. 104 Cases \* \* \* "Colorado Gold Brand Creamery Butter \* \* \*,"  
 page 526  
 (S.D. Calif., 1949)

## Of Incidental Interest

- Barnard et al. v. Carey  
 60 F. Supp. 539 (N.D. Ohio, 1945)  
 Butler v. Kavanagh  
 64 F. Supp. 741 (E.D. Mich., 1945), affirmed 156 F. 2d 158 (C.C.A. 6)

## Trade Correspondence

- |                                  |                                  |
|----------------------------------|----------------------------------|
| TC- 11, Aug. 2, 1939, page 567   | TC-263, May 7, 1940, page 672    |
| TC- 57, Feb. 15, 1940, page 592  | TC-265, May 7, 1940, page 673    |
| TC- 64, Feb. 15, 1940, page 596  | TC-276, May 7, 1940, page 678    |
| TC- 66, Feb. 15, 1940, page 597  | TC-292, May 7, 1940, page 683    |
| TC- 67, Feb. 15, 1940, page 597  | TC-305, Aug. 20, 1940, page 688  |
| TC- 72, Feb. 19, 1940, page 600  | TC-309, Aug. 20, 1940, page 690  |
| TC- 87, Feb. 21, 1940, page 605  | TC-325, Sept. 5, 1940, page 697  |
| TC- 89, Feb. 21, 1940, page 605  | TC-329, Sept. 5, 1940, page 699  |
| TC-108, Feb. 29, 1940, page 612  | TC-339, Sept. 5, 1940, page 703  |
| TC-150, March 7, 1940, page 627  | TC-341, Oct. 28, 1940, page 704  |
| TC-151, March 7, 1940, page 627  | TC-342, Dec. 10, 1940, page 704  |
| TC-166, March 14, 1940, page 634 | TC-344, Dec. 13, 1940, page 705  |
| TC-175, March 14, 1940, page 637 | TC-346, Dec. 18, 1940, page 706  |
| TC-184, March 15, 1940, page 640 | TC-347, Dec. 18, 1940, page 706  |
| TC-194, March 15, 1940, page 644 | TC-358, April 17, 1941, page 712 |
| TC-205, March 21, 1940, page 648 | TC-411, Jan. 10, 1944, page 739  |
| TC-207, March 21, 1940, page 649 | TC-427, April 14, 1945, page 746 |
| TC-222, April 11, 1940, page 656 | TC-2-A, Nov. 5, 1945, page 748   |
| TC-236, April 11, 1940, page 661 |                                  |

## Statements of General Policy or Interpretation

- 21 CFR 3.1, Feb. 3, 1947, page 755  
 21 CFR 3.10, May 20, 1949, page 762

## SECTION 402(a)

## Pertinent 1906 Act Decisions

- United States v. 1,950 Boxes of Macaroni et al.  
 181 Fed. 427 (N.D. Ill., 1910)  
 United States v. 10 Barrels of Olives  
 (E.D. Pa., 1910) White and Gates, "Decisions of Courts in Cases Arising  
 Under the Federal Food and Drugs Act," p. 125  
 United States v. 3,000 Pounds of Frozen Eggs  
 (D. Conn., 1911) White and Gates, "Decisions of Courts in Cases Arising  
 Under the Federal Food and Drugs Act," p. 198  
 United States v. Four Hundred and Forty-Three Cans of Frozen Egg Product  
 193 Fed. 589 (C.C.A. 3, 1912), reversed for want of jurisdiction in the  
 Circuit Court of Appeals, 226 U.S. 172 (1912)  
 Lexington Mill & Elevator Co. v. United States  
 202 Fed. 615 (C.C.A. 8, 1913), affirmed 232 U.S. 399 (1914)  
 United States v. Sprague et al.  
 208 Fed. 419 (E.D. N.Y., 1913)



## SECTION 402 (a)—continued

- Wm. M. Galt & Co. v. United States  
39 App. D.C. 470 (1913)
- Dade v. United States  
40 App. D.C. 94 (1913), certiorari denied 229 U.S. 610 (1913)
- United States of America v. Lexington Mill & Elevator Company  
232 U.S. 399 (1914)
- United States v. Two Hundred Cases of Adulterated Tomato Catsup  
211 Fed. 780 (D. Ore., 1914)
- United States v. 13 Crates of Frozen Eggs  
215 Fed. 584 (C.C.A. 2, 1914)
- United States v. R. C. Boeckel & Co. et al.  
221 Fed. 885 (C.C.A. 1, 1915)
- Weeks v. United States  
224 Fed. 69 (C.C.A. 2, 1915)
- United States v. Coca Cola Company of Atlanta  
241 U.S. 265 (1916)
- United States v. 462 Boxes of Oranges  
249 Fed. 505 (D. Colo., 1917)
- United States v. 1,500 Cases of Tomato Pulp  
(S.D. N.Y., 1918) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 892
- United States v. Krumm  
269 Fed. 848 (E.D. Pa., 1921)
- A. O. Andersen & Co. v. United States  
284 Fed. 542 (C.C.A. 9, 1922)
- W. B. Wood Mfg. Co. v. United States  
286 Fed. 84 (C.C.A. 7, 1923)
- United States v. Two Hundred Cases, More or Less, of Canned Salmon  
289 Fed. 157 (S.D. Tex., 1923)
- United States v. Glezek  
(D. N. Dak., 1923) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1074
- United States v. 496 Cases of Canned Salmon  
(E.D. Mo., 1924) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1099
- United States v. 1,600 Cases of Canned Salmon  
(D. Ore., 1924) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1105
- United States v. 2,205 Cases of Canned Salmon  
(W.D. Tex., 1925) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1133
- Knapp et al. v. Callaway  
52 F. 2d 476 (S.D. N.Y., 1931)
- United States v. 186 Boxes of Whole Tullibeas  
(S.D. N.Y., 1933) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1342
- Van Camp Sea Food Co., Inc. v. United States  
82 F. 2d 365 (C.C.A. 3, 1936)
- United States v. Washington Dehydrated Food Co.  
89 F. 2d 606 (C.C.A. 8, 1937)
- United States v. 133 Cases of Tomato Paste  
22 F. Supp. 515 (E.D. Pa., 1938)
- United States v. One Can of Kololiva  
24 F. Supp. 110 (D. Mass., 1938)
- United States v. 52 Drums Maple Syrup  
110 F. 2d 914 (C.C.A. 2, 1940)

## 1938 Act Decisions

- United States v. 1232 Cases \* \* \* American Beauty Brand Oysters, page 18  
43 F. Supp. 749 (W.D. Mo., 1942)
- United States v. Commercial Creamery Co., page 257  
43 F. Supp. 714 (E.D. Wash., 1942)
- United States v. 1,375 Cases of Tomato Paste, page 13  
(D. Conn., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 3761) Issued May 1943



## SECTION 402 (a)—continued

- United States v. 108 Boxes of Cheddar Cheese, page 33  
(S.D. Iowa, 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 5478) Issued January 1945
- United States v. 998 Cases of Tomato Puree, page 28  
(W.D. Mich., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Food (No. 7850) Issued January 1946
- United States v. 667 Cases of Canned Herring Roe, page 30  
(D. Md., 1942) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8917) Issued February 1947
- United States of America v. 284 Barrels of Dried Eggs, etc., page 48  
52 F. Supp. 661 (W.D. Tenn., 1943)
- In re United States, page 480  
140 F. 2d 19 (C.C.A. 5, 1943)
- United States v. 184 Barrels Dried Whole Eggs, page 59  
53 F. Supp. 652 (E.D. Wis., 1943)
- United States v. Swift & Co. et al., page 449  
53 F. Supp. 1018 (M.D. Ga., 1943)
- United States v. 1851 Cartons \* \* \* Whiting Frosted Fish, page 110  
55 F. Supp. 343 (D. Colo., 1944)
- Triangle Candy Co. et al. v. United States, page 294  
144 F. 2d 195 (C.C.A. 9, 1944), 155 A.L.R. 903
- Joseph v. United States, page 303  
145 F. 2d 74 (C.C.A. 9, 1944), certiorari denied 323 U.S. 776 (1944)
- United States v. Lazere, page 451  
56 F. Supp. 730 (N.D. Iowa, 1944)
- United States v. Gerber Products Co., page 306  
(W.D. Mich., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7808) Issued January 1946
- United States v. 1851 Cartons \* \* \* Whiting Frosted Fish et al., page 134  
146 F. 2d 760 (C.C.A. 10, 1945)
- C. C. Co. v. United States, page 129  
147 F. 2d 820 (C.C.A. 5, 1945)
- United States v. 24 Cans, etc., Butter et al., page 156  
148 F. 2d 365 (C.C.A. 5, 1945), certiorari denied 326 U.S. 752 (1945)
- United States v. Commonwealth Brewing Corporation and Leo Kaufman, page 310  
(D. Mass., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 7926) Issued March 1946
- Rubenstein v. United States, page 460  
153 F. 2d 127 (App. D.C., 1946)
- The James J. Hill (Bowman v. Retzlaff et al.), page 496  
65 F. Supp. 265 (D. Md., 1946)
- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
65 F. Supp. 503 (N.D. Ohio, 1946)
- United States v. Phelps Dodge Mercantile Co., page 189  
157 F. 2d 453 (C.C.A. 9, 1946), certiorari denied 330 U.S. 818 (1947)
- Hygrade Food Products Corporation v. United States, page 468  
160 F. 2d 816 (C.C.A. 8, 1947)
- United States v. Roma Macaroni Factory et al., page 348  
75 F. Supp. 663 (N.D. Calif., 1947)
- 338 Cartons, More or Less, of Butter et al. v. United States, page 222  
165 F. 2d 728 (C.C.A. 4, 1947)
- Salamonie Packing Company v. United States, page 225  
165 F. 2d 205 (C.C.A. 8, 1948), certiorari denied 333 U.S. 863 (1948)
- United States v. Maryland Baking Company and Sara Piem, an individual, page 379  
81 F. Supp. 560 (N.D. Ga., 1948)
- 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
168 F. 2d 361 (C.C.A. 6, 1948)
- Smith v. Great Atlantic & Pacific Tea Co., page 514  
170 F. 2d 474 (C.A. 8, 1948)
- United States v. Runkle Co. et al., page 475  
(N.D. Ohio, 1948)



## SECTION 402 (a)—continued

## Of Incidental Interest

Sligh v. Kirkwood  
237 U.S. 52 (1915)

## Trade Correspondence

TC- 8, May 9, 1939, page 565	TC-213, March 21, 1940, page 652
TC- 12, Reprinted June 1941, page 568	TC-239, April 11, 1940, page 663
TC- 16, Feb. 9, 1940, page 579	TC-284, May 7, 1940, page 681
TC- 44, Feb. 12, 1940, page 586	TC-336, Sept. 5, 1940, page 702
TC- 48, Feb. 12, 1940, page 588	TC-374, Dec. 10, 1941, page 720
TC- 49, Feb. 12, 1940, page 589	TC-377, Dec. 29, 1941, page 721
TC-136, March 7, 1940, page 622	TC-384, May 29, 1942, page 725
TC-144, March 7, 1940, page 625	TC-395, Dec. 18, 1942, page 730
TC-145, March 7, 1940, page 625	TC-406, July 22, 1943, page 736
TC-201, March 21, 1940, page 647	TC-3-A, Nov. 5, 1945, page 750
TC-204, March 21, 1940, page 648	TC-5-A, Nov. 5, 1945, page 751
	TC-8-A, April 4, 1946, page 752

## Statements of General Policy or Interpretation

21 CFR 3.7, November 30, 1948, page 759

## SECTION 402(b)

## Pertinent 1906 Act Decisions

- United States v. St. Louis Coffee & Spice Mills  
189 Fed. 191 (E.D. Mo., 1909)
- United States v. One Hundred Barrels of Vinegar  
188 Fed. 471 (D. Minn., 1911)
- Libby, McNeill & Libby v. United States  
210 Fed. 148 (C.C.A. 4, 1913)
- E. B. Washburn & Co. v. United States  
224 Fed. 395 (C.C.A. 1, 1915)
- United States v. Coca Cola Company of Atlanta  
241 U.S. 265 (1916)
- United States v. Six Barrels of Ground Pepper  
253 Fed. 199 (S.D. N.Y., 1917)
- United States v. Schider  
246 U.S. 519 (1918)
- United States v. 154 Sacks of Oats  
283 Fed. 985 (W.D. Va., 1922)
- W. B. Wood Mfg. Co. v. United States  
286 Fed. 84 (C.C.A. 7, 1923)
- W. B. Wood Mfg. Co. v. United States  
292 Fed. 133 (C.C.A. 8, 1923)
- United States v. 24 $\frac{7}{8}$  Gallons of Smack  
(E.D. Wis., 1926) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1181
- United States v. Ten Cases \* \* \* Bred Spred, etc.  
49 F. 2d 87 (C.C.A. 8, 1931)
- United States v. 800 Sacks Barley Mixed Oats  
64 F. 2d 678 (C.C.A. 5, 1933)
- United States v. 492 Cases \* \* \* Orange Juice  
20 F. Supp. 520 (E.D. La., 1937), affirmed 96 F. 2d 972 (C.C.A. 5)
- United States v. Nesbitt Fruit Products, Inc.  
96 F. 2d 972 (C.C.A. 5, 1938), affirming 20 F. Supp. 520 (E.D. La.)

## 1938 Act Decisions

- Land O'Lakes Creameries, Inc. et al. v. McNutt et al., page 412  
132 F. 2d 653 (C.C.A. 8, 1943)
- Helco Products Co., Inc. v. McNutt et al., page 477  
137 F. 2d 681 (App. D.C., 1943)



## SECTION 402 (b)—continued

- United States v. 55 Cases Popped Corn et al., page 56  
62 F. Supp. 843 (D. Idaho, 1943)
- United States v. 2 Bags \* \* \* Poppy Seeds, page 78  
54 F. Supp. 706 (N.D. Ohio, 1944)
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)
- United States v. Two Bags \* \* \* Poppy Seeds, page 135  
147 F. 2d 123 (C.C.A. 6, 1945)
- United States v. 254 Cases \* \* \* "Baby Brand Tomato Sauce," etc., page 162  
63 F. Supp. 916 (E.D. Ark., 1945)
- United States v. 36 Drums of Pop'N Oil, page 215  
164 F. 2d 250 (C.C.A. 5, 1947)
- United States v. 99 Cases \* \* \* Peach Fountain Fruit, etc., page 245  
(E.D. Tenn., 1948)

## Of Incidental Interest

- United States v. Carolene Products Co.  
304 U.S. 144 (1938)
- Carolene Products Company et al v. United States  
323 U.S. 18 (1944)

## Trade Correspondence

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| TC- 12, Reprinted June 1941, page 568 | TC-175, March 14, 1940, page 637 |
| TC- 49, Feb. 12, 1940, page 589       | TC-185, March 15, 1940, page 641 |
| TC- 50, Feb. 12, 1940, page 589       | TC-195, March 15, 1940, page 645 |
| TC- 87, Feb. 21, 1940, page 605       | TC-201, March 21, 1940, page 647 |
| TC- 89, Feb. 21, 1940, page 605       | TC-213, March 21, 1940, page 652 |
| TC- 90, Feb. 21, 1940, page 606       | TC-218, March 21, 1940, page 654 |
| TC- 91, Feb. 21, 1940, page 606       | TC-233, April 11, 1940, page 660 |
| TC- 92, Feb. 21, 1940, page 607       | TC-239, April 11, 1940, page 663 |
| TC-154, March 7, 1940, page 629       | TC-311, Aug. 20, 1940, page 691  |
|                                       | TC-405, July 16, 1943, page 736  |
|                                       | TC-8-A, April 4, 1946, page 752  |

## Statements of General Policy or Interpretation

- 21 CFR 3.1, February 3, 1947, page 755
- 21 CFR 3.10, May 20, 1949, page 762

## SECTION 402(c)

## Pertinent 1906 Act Decisions

- W. B. Wood Mfg. Co. v. United States  
286 Fed. 84 (C.C.A. 7, 1923)

## Trade Correspondence

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| TC- 12, Reprinted June 1941, page 568 | TC-182, March 15, 1940, page 640 |
| TC- 58, Feb. 15, 1940, page 592       | TC-219, March 21, 1940, page 655 |
| TC-162, March 14, 1940, page 632      | TC-332, Sept. 5, 1940, page 700  |
| TC-171, March 14, 1940, page 636      | TC-335, Sept. 5, 1940, page 701  |

## SECTION 402(d)

## Pertinent 1906 Act Decisions

- French Silver Dragée Co. v. United States  
179 Fed. 824 (C.C.A. 2, 1910)
- United States v. R. C. Boeckel & Co. et al.  
221 Fed. 885 (C.C.C. 1, 1915)



## SECTION 402 (d)—continued

## Trade Correspondence

TC- 12, Reprinted June 1941, page 568	TC- 65, Feb. 15, 1940, page 596
TC- 18, Feb. 9, 1940, page 579	TC-130, March 7, 1940, page 620
TC- 19, Feb. 9, 1940, page 580	TC-238, April 11, 1940, page 662
TC- 63, Feb. 15, 1940, page 595	TC-239, April 11, 1940, page 663
	TC-317, Aug. 20, 1940, page 694

## SECTION 403(a)

## Regulations

21 CFR, Cum. Supp., 2.7

## Pertinent 1906 Act Decisions

- United States v. 100 Cases of Tepee Apples et al.  
179 Fed. 985 (W.D. Mo., 1908)
- United States v. Scanlon  
180 Fed. 485 (N.D. Ohio, 1908)
- In re Wilson  
168 Fed. 566 (D. R.I., 1909)
- United States v. 68 Cases of Syrup  
172 Fed. 781 (E.D. Ill., 1909)
- United States v. Boeckmann  
176 Fed. 382 (E.D. N.Y., 1910), writ of error dismissed 218 U.S. 684 (1910)
- United States v. Schurman et al.  
177 Fed. 581 (W.D. Mich., 1910)
- Brina v. United States  
179 Fed. 373 (C.C.A. 2, 1910)
- Nave-McCord Mercantile Co. v. United States  
182 Fed. 46 (C.C.A. 8, 1910)
- United States v. 10 Barrels of Vinegar  
186 Fed. 399 (E.D. Wis., 1911)
- United States v. Thompson & Taylor Spice Co.  
198 Fed. 565 (N.D. Ill., 1912)
- United States v. Sweet Valley Wine Co.  
208 Fed. 85 (N.D. Ohio, 1913)
- Libby, McNeill & Libby v. United States  
210 Fed. 148 (C.C.A. 4, 1913)
- United States v. Five Cases of Hurdle Brand Holland Gin  
(D. of Col., 1913) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 549
- United States v. 267 Boxes of Macaroni  
225 Fed. 79 (W.D. Pa., 1915)
- Mitchell v. United States  
229 Fed. 357 (C.C.A. 2, 1916)
- United States v. Coca Cola Company of Atlanta  
241 U.S. 265 (1916)
- Weeks v. United States  
245 U.S. 618 (1918), affirming 224 Fed. 64 (C.C.A. 2)
- United States v. Schider  
246 U.S. 519 (1918)
- Duffy-Mott Co. v. United States  
285 Fed. 737 (C.C.A. 3, 1923)
- Newton Tea & Spice Co. v. United States  
288 Fed. 475 (C.C.A. 6, 1923), affirming 275 Fed. 394 (S.D. Ohio)
- United States v. Ninety-Five Barrels \* \* \* Alleged Apple Cider Vinegar  
265 U.S. 438 (1924)
- United States v. Ten Cases \* \* \* Bred Spred, etc.  
49 F. 2d 87 (C.C.A. 8, 1931)
- United States v. 52 One-Gallon Cans, More or Less, of Salad Oil  
16 F. Supp. 385 (D. Conn., 1935)



## SECTION 403 (a)—continued

- United States v. Feeders' Supply & Mfg. Co.  
15 F. Supp. 385 (W.D. Mo., 1936)
- United States v. 397 Cases, etc., of Salad Oil  
16 F. Supp. 387 (D. N.J., 1936)
- United States v. Great Atlantic & Pacific Tea Co.  
92 F. 2d 610 (C.C.A. 2, 1937), 113 A.L.R. 961
- United States v. 492 Cases \* \* \* Orange Juice  
20 F. Supp. 520 (E.D. La., 1937), affirmed 96 F. 2d 972 (C.C.A. 5)
- United States v. Nesbitt Fruit Products, Inc.  
96 F. 2d 972 (C.C.A. 5, 1938), affirming 20 F. Supp. 520 (E.D. La.)
- United States v. One Can of Kololiva  
24 F. Supp. 110 (D. Mass., 1938)

## 1938 Act Decisions

- United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942
- United States v. 650 Bags of Roasted Malted Cereal et al., page 51  
(W.D. Mo., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 6403) Issued June 1945
- United States v. 254 Cases \* \* \* "Baby Brand Tomato Sauce," etc., page 162  
63 F. Supp. 916 (E.D. Ark., 1945)
- Barnes et al. v. United States, page 285  
142 F. 2d 648 (C.C.A. 9, 1944)
- United States v. G. Fred Obrecht, page 456  
(D. Md., 1945) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 8894) Issued February 1947
- United States v. 14 Cartons \* \* \* "Ayd's Candy \* \* \*," page 182  
(E.D. Mo., 1946)
- United States v. 12 Bottles of Esterex, page 523  
(E.D. Mo., 1946) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Foods (No. 12833) Issued February 1949
- United States v. Bess J. Levine, Trading as Miracle Food Company, page 367  
(E.D. Pa., 1948)
- United States v. 104 Cases \* \* \* "Colorado Gold Brand Creamery Butter \* \* \*," page 526  
(S.D. Calif., 1949)

## Of Incidental Interest

- Donaldson v. Read Magazine, Inc. et al.  
333 U.S. 178 (1948)

## Trade Correspondence

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| TC- 12, Reprinted June 1941, page 568 | TC-138, March 7, 1940, page 623  |
| TC- 36, Feb. 9, 1940, page 584        | TC-147, March 7, 1940, page 626  |
| TC- 50, Feb. 12, 1940, page 589       | TC-148, March 7, 1940, page 626  |
| TC- 51, Feb. 12, 1940, page 589       | TC-155, March 7, 1940, page 629  |
| TC- 71, Feb. 19, 1940, page 600       | TC-158, March 7, 1940, page 630  |
| TC- 72, Feb. 19, 1940, page 600       | TC-169, March 14, 1940, page 635 |
| TC- 73, Feb. 19, 1940, page 600       | TC-211, March 21, 1940, page 652 |
| TC- 74, Feb. 19, 1940, page 600       | TC-215, March 21, 1940, page 653 |
| TC- 80, Feb. 21, 1940, page 603       | TC-225, April 11, 1940, page 657 |
| TC- 87, Feb. 21, 1940, page 605       | TC-230, April 11, 1940, page 659 |
| TC- 88, Feb. 21, 1940, page 605       | TC-247, April 25, 1940, page 666 |
| TC- 89, Feb. 21, 1940, page 605       | TC-255, April 25, 1940, page 669 |
| TC- 90, Feb. 21, 1940, page 606       | TC-256, April 25, 1940, page 669 |
| TC- 92, Feb. 21, 1940, page 607       | TC-262, May 7, 1940, page 672    |
| TC- 99, Feb. 21, 1940, page 609       | TC-263, May 7, 1940, page 672    |
| TC-106, Feb. 29, 1940, page 611       | TC-264, May 7, 1940, page 673    |
| TC-127, March 7, 1940, page 619       | TC-275, May 7, 1940, page 677    |
| TC-133, March 7, 1940, page 621       | TC-281, May 7, 1940, page 680    |
| TC-135, March 7, 1940, page 622       | TC-283, May 7, 1940, page 680    |
| TC-137, March 7, 1940, page 623       | TC-286, May 7, 1940, page 681    |
|                                       | TC-289, May 7, 1940, page 682    |



## SECTION 403 (a)—continued

TC-290, May	7, 1940, page 682	TC-363, July	7, 1941, page 715
TC-291, May	7, 1940, page 683	TC-379, Jan.	23, 1942, page 723
TC-293, May	7, 1940, page 684	TC-388, July	27, 1942, page 726
TC-297, May	7, 1940, page 685	TC-404, July	13, 1943, page 735
TC-298, May	7, 1940, page 686	TC-405, July	16, 1943, page 736
TC-300, May	7, 1940, page 686	TC-407, Aug.	5, 1943, page 737
TC-317, Aug.	20, 1940, page 694	TC-408, Sept.	9, 1943, page 738
TC-320, Aug.	20, 1940, page 695	TC-411, Jan.	10, 1944, page 739
TC-321, Sept.	5, 1940, page 695	TC-416, May	29, 1944, page 742
TC-359, April	22, 1941, page 712	TC-2-A, Nov.	5, 1945, page 748

## Statements of General Policy or Interpretation

21 CFR 3.6, October 20, 1948, page 758

## Pertinent Federal Trade Commission Act Decisions

- Federal Trade Commission v. Good-Grape Co.  
45 F. 2d 70 (C.C.A. 6, 1930)
- Federal Trade Commission v. Morrissey  
47 F. 2d 101 (C.C.A. 7, 1931)
- H. N. Heusner & Son v. Federal Trade Commission  
106 F. 2d 596 (C.C.A. 3, 1939)
- El Moro Cigar Company v. Federal Trade Commission  
107 F. 2d 429 (C.C.A. 4, 1939)
- United Corporation et al. v. Federal Trade Commission  
110 F. 2d 473 (C.C.A. 4, 1940)
- Fresh Grown Preserve Corporation et al v. Federal Trade Commission  
125 F. 2d 917 (C.C.A. 2, 1942)
- Bockenstette et al. v. Federal Trade Commission  
134 F. 2d 369 (C.C.A. 10, 1943)
- Fresh Grown Preserve Corporation et al. v. Federal Trade Commission  
139 F. 2d 200 (C.C.A. 2, 1943)
- A. P. W. Paper Co., Inc. v. Federal Trade Commission  
149 F. 2d 424 (C.C.A. 2, 1945), affirmed 328 U.S. 193 (1946)
- Perloff et al. v. Federal Trade Commission  
150 F. 2d 757 (C.C.A. 3, 1945)

## Opinions of the Attorney General

- 24 Ops. Att'y. Gen. 125, September 20, 1902
- 24 Ops. Att'y. Gen. 675, June 18, 1903
- 24 Ops. Att'y. Gen. 695, June 22, 1903
- 25 Ops. Att'y. Gen. 142, April 19, 1904
- 26 Ops. Att'y. Gen. 216, April 10, 1907
- 26 Ops. Att'y. Gen. 262, May 29, 1907
- 26 Ops. Att'y. Gen. 474, January 11, 1908
- 26 Ops. Att'y. Gen. 541, March 25, 1908
- 27 Ops. Att'y. Gen. 47, August 3, 1908
- 27 Ops. Att'y. Gen. 202, February 19, 1909
- 28 Ops. Att'y. Gen. 455, October 19, 1910
- 34 Ops. Att'y. Gen. 221, July 7, 1924

## SECTION 403(b)

## Pertinent 1906 Act Decisions

- United States v. Fifty Barrels of Whiskey  
165 Fed. 966 (D. Md., 1908)
- Brina v. United States  
179 Fed. 373 (C.C.A. 2, 1910)
- United States v. Ten Barrels of Vinegar  
186 Fed. 399 (E.D. Wis., 1911)
- United States v. One Car Load of Corno Horse and Mule Feed  
188 Fed. 453 (M.D. Ala., 1911)



## SECTION 403 (b)—continued

- Von Bremen et al. v. United States  
192 Fed. 904 (C.C.A. 2, 1912)
- United States v. Seventy-Five Boxes of Alleged Pepper  
198 Fed. 934 (D. N.J., 1912)
- Schraubstadter, et al. v. United States  
199 Fed. 568 (C.C.A. 9, 1912)
- United States v. Thirty Cases \* \* \* Grenadine Syrup  
199 Fed. 932 (D. Mass., 1912)
- United States v. Five Cases of Champagne  
205 Fed. 817 (N.D. N.Y., 1913)
- F. B. Washburn & Co. v. United States  
224 Fed. 395 (C.C.A. 1, 1915)
- United States v. Sixty Barrels of Wine  
225 Fed. 846 (W.D. Mo., 1915)
- Weeks v. United States  
245 U.S. 618 (1918), affirming 224 Fed. 64 (C.C.A. 2)
- United States v. Krumm  
269 Fed. 848 (E.D. Pa., 1921)
- United States v. 52 One-Gallon Cans \* \* \* of Salad Oil  
16 F. Supp. 385 (D. Conn., 1935)

## 1938 Act Decisions

- United States v. 55 Cases Popped Corn et al., page 56  
62 F. Supp. 843 (D. Idaho, 1943)
- United States v. 254 Cases \* \* \* "Baby Brand Tomato Sauce," etc., page 162  
63 F. Supp. 916 (E.D. Ark., 1945)
- United States v. G. Fred Obrecht, page 456  
(D. Md., 1945) Notices of Judgment Under the Federal Food, Drug, and  
Cosmetic Act, Foods (No. 8894) Issued February 1947

## Trade Correspondence

- |                                  |                                  |
|----------------------------------|----------------------------------|
| TC- 33, Feb. 9, 1940, page 583   | TC-247, April 25, 1940, page 666 |
| TC- 47, Feb. 12, 1940, page 588  | TC-255, April 25, 1940, page 669 |
| TC-127, March 7, 1940, page 619  | TC-262, May 7, 1940, page 672    |
| TC-133, March 7, 1940, page 621  | TC-264, May 7, 1940, page 673    |
| TC-135, March 7, 1940, page 622  | TC-293, May 7, 1940, page 684    |
| TC-155, March 7, 1940, page 629  | TC-297, May 7, 1940, page 685    |
| TC-169, March 14, 1940, page 635 | TC-298, May 7, 1940, page 686    |
| TC-230, April 11, 1940, page 659 | TC-320, Aug. 20, 1940, page 695  |

## Statements of General Policy or Interpretation

- 21 CFR 3.6, October 20, 1948, page 758

## Opinions of the Attorney General

- 26 Ops. Att'y. Gen. 216, April 10, 1907
- 26 Ops. Att'y. Gen. 262, May 29, 1907
- 26 Ops. Att'y. Gen. 474, January 11, 1908
- 26 Ops. Att'y. Gen. 541, March 25, 1908
- 27 Ops. Att'y. Gen. 47, August 3, 1908
- 27 Ops. Att'y. Gen. 202, February 19, 1909
- 28 Ops. Att'y. Gen. 455, October 19, 1910
- 34 Ops. Att'y. Gen. 221, July 7, 1924

## SECTION 403(c)

## Pertinent 1906 Act Decisions

- United States v. Sixty-Eight Cases of Syrup  
172 Fed. 781 (E.D. Ill., 1909)
- United States v. Seven Hundred and Seventy-Nine Cases of Molasses  
174 Fed. 325 (C.C.A. 8, 1909)



**SECTION 403 (c)—continued**

- Frank, et al. v. United States  
192 Fed. 864 (C.C.A. 6, 1911), affirming 189 Fed. 195 (S.D. Ohio)
- Husson Mfg. Co. v. United States  
192 Fed. 920 (C.C.A. 5, 1912)
- William Henning & Co. v. United States  
193 Fed. 52 (C.C.A. 5, 1912)
- United States v. Five Cases of Champagne  
205 Fed. 817 (N.D. N.Y., 1913)
- Weeks v. United States  
245 U.S. 618 (1918), affirming 224 Fed. 64 (C.C.A. 2)
- United States v. Schider  
246 U.S. 519 (1918)
- Duffy-Mott Co. v. United States  
285 Fed. 737 (C.C.A. 3, 1923)

**1938 Act Decisions**

- Land O'Lakes Creameries, Inc., et al. v. McNutt et al., page 412  
132 F. 2d 653 (C.C.A. 8, 1943)

**Trade Correspondence**

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| TC- 12, Reprinted June 1941, page 568 | TC-184, March 15, 1940, page 640 |
| TC-143, March 7, 1940, page 625       | TC-234, April 11, 1940, page 660 |
| TC-151, March 7, 1940, page 627       | TC-275, May 7, 1940, page 677    |
| TC-177, March 14, 1940, page 638      | TC-285, May 7, 1940, page 681    |
|                                       | TC-358, April 17, 1941, page 712 |

**Opinions of the Attorney General**

- 26 Ops. Att'y. Gen. 216, April 10, 1907  
26 Ops. Att'y. Gen. 262, May 29, 1907  
26 Ops. Att'y. Gen. 474, January 11, 1908  
26 Ops. Att'y. Gen. 541, March 25, 1908

**SECTION 403(d)****1938 Act Decisions**

- United States v. 149 Gift Packages, page 54  
52 F. Supp. 993 (E.D. N.Y., 1943)
- United States v. 738 Cases \* \* \* "Jiffy-Lou Vanilla Flavor Pudding," page 171  
71 F. Supp. 279 (D. Ariz., 1946)
- United States v. Cataldo, page 193  
157 F. 2d 802 (C.C.A. 1, 1946)
- United States v. 116 Boxes \* \* \* "Arden Assorted Candy Drops," etc., page 247  
80 F. Supp. 911 (D. Mass., 1948)

**Trade Correspondence**

- |                                      |                                  |
|--------------------------------------|----------------------------------|
| TC-12, Reprinted June 1941, page 568 | TC-161, March 14, 1940, page 632 |
|                                      | TC-318, Aug. 20, 1940, page 694  |

**Statements of General Policy or Interpretation**

- 21 CFR 3.1, February 3, 1947, page 755



## SECTION 403(e)

## Regulations

21 CFR, Cum. Supp., 2.8

## Pertinent 1906 Act Decisions

United States v. Rigney &amp; Co.

220 Fed. 734 (E.D. N.Y., 1915)

United States v. The Merchants Biscuit Co.

(D. Colo., 1924) White and Gates, "Decisions of Courts in Cases Under the Federal Food and Drugs Act," p. 1129

United States v. Shreveport Grain &amp; Elevator Co.

287 U.S. 77 (1932)

United States v. Centralia Dairy Co.

60 F. 2d 141 (W.D. Wash., 1932)

United States v. 462 Bags of Flour

8 F. Supp. 79 (W.D. La., 1934)

United States v. Feeders' Supply &amp; Mfg. Co.

15 F. Supp. 385 (W.D. Mo., 1936)

United States v. Kraft Phenix Cheese Corporation

18 F. Supp. 60 (S.D. N.Y., 1936)

United States v. Great Atlantic &amp; Pacific Tea Co.

92 F. 2d 610 (C.C.A. 2, 1937), 113 A.L.R. 961

## Trade Correspondence

TC- 7, Feb. 28, 1939, page 564

TC- 12, Reprinted June 1941, page 568

TC- 17, Feb. 9, 1940, page 579

TC- 18, Feb. 9, 1940, page 579

TC- 19, Feb. 9, 1940, page 580

TC- 28, Feb. 9, 1940, page 582

TC- 37, Feb. 9, 1940, page 584

TC- 70, Feb. 19, 1940, page 599

TC- 77, Feb. 19, 1940, page 602

TC-141, March 7, 1940, page 624

TC-155, March 7, 1940, page 629

TC-156, March 7, 1940, page 629

TC-157, March 7, 1940, page 630

TC-168, March 14, 1940, page 634

TC-178, March 14, 1940, page 638

TC-179, March 15, 1940, page 639

TC-197, March 15, 1940, page 645

TC-205, March 21, 1940, page 648

TC-206, March 21, 1940, page 649

TC-214, March 21, 1940, page 653

TC-217, March 21, 1940, page 654

TC-226, April 11, 1940, page 658

TC-232, April 11, 1940, page 660

TC-235, April 11, 1940, page 661

TC-242, April 25, 1940, page 664

TC-252, April 25, 1940, page 667

TC-257, April 25, 1940, page 670

TC-258, April 25, 1940, page 670

TC-266, May 7, 1940, page 673

TC-272, May 7, 1940, page 676

TC-273, May 7, 1940, page 676

TC-277, May 7, 1940, page 678

TC-282, May 7, 1940, page 680

TC-288, May 7, 1940, page 682

TC-299, May 7, 1940, page 686

TC-335, Sept. 5, 1940, page 701

TC-341, Oct. 28, 1940, page 704

## Statements of General Policy or Interpretation

21 CFR 3.2, June 2, 1947, page 756

## Opinions of the Attorney General

30 Ops. Att'y. Gen. 222, August 25, 1913

31 Ops. Att'y Gen. 150, August 28, 1917

## SECTION 403(f)

## Regulations

21 CFR, Cum. Supp., 2.9

## Trade Correspondence

TC- 7, Feb. 28, 1939, page 564

TC- 12, Reprinted June 1941, page 568

TC- 31, Feb. 9, 1940, page 583

TC- 47, Feb. 12, 1940, page 588

TC- 52, Feb. 12, 1940, page 590

TC- 96, Feb. 21, 1940, page 608

TC- 97, Feb. 21, 1940, page 609

TC-150, March 7, 1940, page 627

TC-152, March 7, 1940, page 628



**SECTION 403 (f)—continued**

TC-205, March 21, 1940, page 648	TC-266, May 7, 1940, page 673
TC-217, March 21, 1940, page 654	TC-273, May 7, 1940, page 676
TC-223, April 11, 1940, page 657	TC-288, May 7, 1940, page 682
TC-240, April 25, 1940, page 663	TC-295, May 7, 1940, page 684
TC-242, April 25, 1940, page 664	

**SECTION 403(g)****Regulations**

21 CFR, 1943 Supp., 2.14; 8 F.R. 9936

**Pertinent 1906 Act Decisions**

United States v. Frank et al.  
189 Fed. 195 (S.D. Ohio, 1911), affirmed 192 Fed. 864 (C.C.A. 6)  
United States v. 154 Sacks of Oats  
294 Fed. 340 (W.D. Va., 1923)

**1938 Act Decisions**

United States v. 306 Cases \* \* \* "Sandford Tomato Catsup with Preservative,"  
page 115  
55 F. Supp. 725 (E.D. N.Y., 1944)  
United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)  
Libby, McNeill & Libby v. United States, page 145  
148 F. 2d 71 (C.C.A. 2, 1945)  
United States v. 99 Cases \* \* \* Peach Fountain Fruit, etc., page 245  
(E.D. Tenn., 1948)

**Of Incidental Interest**

Barnard et al. v. Carey  
60 F. Supp. 539 (N.D. Ohio, 1945)  
Butler v. Kavanagh  
64 F. Supp. 741 (E.D. Mich., 1945), affirmed 156 F. 2d 158 (C.C.A. 6)  
United States v. Carolene Products Co.  
304 U.S. 144 (1938)  
Carolene Products Company et al. v. United States  
323 U.S. 18 (1944)

**Trade Correspondence**

TC- 57, Feb. 15, 1940, page 592	TC-292, May 7, 1940, page 683
TC-108, Feb. 29, 1940, page 612	TC-305, Aug. 20, 1940, page 688
TC-151, March 7, 1940, page 627	TC-325, Sept. 5, 1940, page 697
TC-184, March 15, 1940, page 640	TC-339, Sept. 5, 1940, page 703
TC-205, March 21, 1940, page 648	TC-427, April 14, 1945, page 746
TC-207, March 21, 1940, page 649	

**SECTION 403(h)****1938 Act Decisions**

United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)



SECTION 403(i)

Regulations

21 CFR, Cum. Supp., 2.10

1938 Act Decisions

United States v. 650 Bags of Roasted Malted Cereal et al., page 51  
(W.D. Mo., 1943) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Foods (No. 6403) Issued June 1945

Trade Correspondence

TC- 7, Feb. 28, 1939, page 564	TC-209, March 21, 1940, page 651
TC- 11, Aug. 2, 1939, page 567	TC-210, March 21, 1940, page 651
TC- 12, Reprinted June 1941, page 568	TC-212, March 21, 1940, page 652
TC- 15, Feb. 9, 1940, page 578	TC-214, March 21, 1940, page 653
TC- 18, Feb. 9, 1940, page 579	TC-216, March 21, 1940, page 654
TC- 19, Feb. 9, 1940, page 580	TC-217, March 21, 1940, page 654
TC- 32, Feb. 9, 1940, page 583	TC-221, April 11, 1940, page 655
TC- 35, Feb. 9, 1940, page 584	TC-223, April 11, 1940, page 657
TC- 38, Feb. 9, 1940, page 585	TC-225, April 11, 1940, page 657
TC- 50, Feb. 12, 1940, page 589	TC-232, April 11, 1940, page 660
TC- 53, Feb. 12, 1940, page 590	TC-234, April 11, 1940, page 660
TC- 62, Feb. 15, 1940, page 594	TC-235, April 11, 1940, page 661
TC- 63, Feb. 15, 1940, page 595	TC-236, April 11, 1940, page 661
TC- 64, Feb. 15, 1940, page 596	TC-238, April 11, 1940, page 662
TC- 65, Feb. 15, 1940, page 596	TC-240, April 25, 1940, page 663
TC- 66, Feb. 15, 1940, page 597	TC-241, April 25, 1940, page 664
TC- 67, Feb. 15, 1940, page 597	TC-242, April 25, 1940, page 664
TC- 69, Feb. 19, 1940, page 599	TC-247, April 25, 1940, page 666
TC- 93, Feb. 21, 1940, page 607	TC-248, April 25, 1940, page 666
TC- 94, Feb. 21, 1940, page 607	TC-255, April 25, 1940, page 669
TC-101, Feb. 29, 1940, page 610	TC-256, April 25, 1940, page 669
TC-108, Feb. 29, 1940, page 612	TC-258, April 25, 1940, page 670
TC-118, Feb. 29, 1940, page 615	TC-259, April 25, 1940, page 671
TC-119, Feb. 29, 1940, page 616	TC-261, May 7, 1940, page 672
TC-120, Feb. 29, 1940, page 616	TC-263, May 7, 1940, page 672
TC-124, Feb. 29, 1940, page 618	TC-273, May 7, 1940, page 676
TC-125, Feb. 29, 1940, page 619	TC-275, May 7, 1940, page 677
TC-126, March 7, 1940, page 619	TC-276, May 7, 1940, page 678
TC-134, March 7, 1940, page 621	TC-278, May 7, 1940, page 679
TC-137, March 7, 1940, page 623	TC-279, May 7, 1940, page 679
TC-138, March 7, 1940, page 623	TC-285, May 7, 1940, page 681
TC-139, March 7, 1940, page 623	TC-296, May 7, 1940, page 685
TC-142, March 7, 1940, page 624	TC-307, Aug. 20, 1940, page 689
TC-156, March 7, 1940, page 629	TC-308, Aug. 20, 1940, page 689
TC-159, March 14, 1940, page 631	TC-309, Aug. 20, 1940, page 690
TC-166, March 14, 1940, page 634	TC-315, Aug. 20, 1940, page 692
TC-168, March 14, 1940, page 634	TC-322, Sept. 5, 1940, page 696
TC-169, March 14, 1940, page 635	TC-329, Sept. 5, 1940, page 699
TC-177, March 14, 1940, page 638	TC-341, Oct. 28, 1940, page 704
TC-180, March 15, 1940, page 639	TC-342, Dec. 10, 1940, page 704
TC-185, March 15, 1940, page 641	TC-344, Dec. 13, 1940, page 705
TC-194, March 15, 1940, page 644	TC-345, Dec. 18, 1940, page 705
TC-195, March 15, 1940, page 645	TC-346, Dec. 18, 1940, page 706
TC-197, March 15, 1940, page 645	TC-353, Jan. 21, 1941, page 710
TC-201, March 21, 1940, page 647	TC-358, April 17, 1941, page 712
TC-202, March 21, 1940, page 647	TC-387, June 23, 1942, page 726
TC-205, March 21, 1940, page 648	TC-403, June 7, 1943, page 734
	TC-411, Jan. 10, 1944, page 739

Statements of General Policy or Interpretation

21 CFR 3.10, May 20, 1949, page 762



**SECTION 403(j)****Regulations**

21 CFR, Cum. Supp., 2.11.

21 CFR, Cum. Supp., 125.1 *et seq.*, 6 F.R. 5925**Trade Correspondence**

TC- 79, Feb. 21, 1940, page 602  
 TC-311, Aug. 20, 1940, page 691  
 TC-315, Aug. 20, 1940, page 692  
 TC-363, July 7, 1941, page 715  
 TC-379, Jan. 23, 1942, page 723  
 TC-381, Jan. 23, 1942, page 724  
 TC-387, June 23, 1942, page 726  
 TC-388, July 27, 1942, page 726

TC-395, Dec. 18, 1942, page 730  
 TC-401, April 19, 1943, page 734  
 TC-404, July 13, 1943, page 735  
 TC-408, Sept. 9, 1943, page 738  
 TC-411, Jan. 10, 1944, page 739  
 TC-2-A, Nov. 5, 1945, page 748  
 TC-8-A, April 4, 1946, page 752

**SECTION 403(k)****Regulations**

21 CFR, Cum. Supp., 2.12

**1938 Act Decisions**

Libby, McNeill & Libby, v. United States, page 145  
 148 F. 2d 71 (C.C.A. 2, 1945)

**Trade Correspondence**

TC- 12, Reprinted June 1941, page 568  
 TC- 30, Feb. 9, 1940, page 582  
 TC- 68, Feb. 19, 1940, page 598  
 TC- 69, Feb. 19, 1940, page 599  
 TC- 72, Feb. 19, 1940, page 600  
 TC-104, Feb. 29, 1940, page 611  
 TC-143, March 7, 1940, page 625  
 TC-167, March 14, 1940, page 634  
 TC-172, March 14, 1940, page 636  
 TC-173, March 14, 1940, page 636  
 TC-175, March 14, 1940, page 637  
 TC-176, March 14, 1940, page 638  
 TC-177, March 14, 1940, page 638  
 TC-195, March 15, 1940, page 645  
 TC-198, March 15, 1940, page 646  
 TC-203, March 21, 1940, page 647

TC-213, March 21, 1940, page 652  
 TC-221, April 11, 1940, page 655  
 TC-233, April 11, 1940, page 660  
 TC-237, April 11, 1940, page 662  
 TC-240, April 25, 1940, page 663  
 TC-241, April 25, 1940, page 664  
 TC-265, May 7, 1940, page 673  
 TC-275, May 7, 1940, page 677  
 TC-282, May 7, 1940, page 680  
 TC-285, May 7, 1940, page 681  
 TC-322, Sept. 5, 1940, page 696  
 TC-340, Sept. 17, 1940, page 703  
 TC-387, June 23, 1942, page 726  
 TC-405, July 16, 1943, page 736  
 TC-406, July 22, 1943, page 736

**Statements of General Policy or Interpretation**

21 CFR 3.10, May 20, 1949, page 762

**SECTION 405****Regulations**

21 CFR, Cum. Supp., 2.13

**Pertinent 1906 Act Decisions**

United States v. 52 Drums Maple Syrup, etc.  
 110 F. 2d 914 (C.C.A. 2, 1940)



## SECTION 405—continued

## 1938 Act Decisions

- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
 65 F. Supp. 503 (N.D. Ohio, 1946)  
 United States v. Sullivan, page 350  
 332 U.S. 689 (1948)

## Trade Correspondence

- |                                  |                                 |
|----------------------------------|---------------------------------|
| TC- 81, Feb. 21, 1940, page 603  | TC-277, May 7, 1940, page 678   |
| TC-182, March 15, 1940, page 640 | TC-322, Sept. 5, 1940, page 696 |
| TC-274, May 7, 1940, page 677    |                                 |

## SECTION 406(a)

## Regulations

- 21 CFR, 1944 Supp., 120.1, 9 F.R. 11836

## 1938 Act Decisions

- United States v. 1232 Cases \* \* \* American Beauty Brand Oysters, page 18  
 43 F. Supp. 749 (W.D. Mo., 1942)  
 United States v. 935 Cases \* \* \* Tomato Puree, page 179  
 65 F. Supp. 503 (N.D. Ohio, 1946)  
 United States v. Commonwealth Brewing Corporation and Leo Kaufman, page 310  
 (D. Mass., 1945) Notices of Judgment Under the Federal Food, Drug,  
 and Cosmetic Act, Foods (No. 7926) Issued March 1946  
 Washington State Apple Advertising Commission et al. v. Federal Security  
 Administrator, page 440  
 156 F. 2d 589 (C.C.A. 9, 1946)

## Trade Correspondence

- |                                 |                                |
|---------------------------------|--------------------------------|
| TC-136, March 7, 1940, page 622 | TC-3-A, Nov. 5, 1945, page 750 |
| TC-377, Dec. 29, 1941, page 721 | TC-5-A, Nov. 5, 1945, page 751 |

## Statements of General Policy or Interpretation

- 21 CFR 3.7, November 30, 1948, page 759

## SECTION 406(b)

## Regulations

- Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.  
 21 CFR, Cum. Supp., 135.01 *et seq.*, as amended 21 CFR, 1946 Supp., 135.15

## 1938 Act Decisions

- United States v. 935 Cases \* \* \* Tomato Puree, page 179  
 65 F. Supp. 503 (N.D. Ohio, 1946)

## Trade Correspondence

- |                                       |                                  |
|---------------------------------------|----------------------------------|
| TC- 12, Reprinted June 1941, page 568 | TC-182, March 15, 1940, page 640 |
| TC- 58, Feb. 15, 1940, page 592       | TC-219, March 21, 1940, page 655 |
| TC-162, March 14, 1940, page 632      | TC-332, Sept. 5, 1940, page 700  |
| TC-171, March 14, 1940, page 636      | TC-335, Sept. 5, 1940, page 701  |
|                                       | TC-359, April 22, 1941, page 712 |



**SECTION 501(a)****1938 Act Decisions**

United States v. Crescent-Kelvan Company, et al., page 359  
164 F. 2d 582 (C.C.A. 3, 1948)

**Trade Correspondence**

TC-128, March 7, 1940, page 619 TC-251, April 25, 1940, page 667

**SECTION 501(b)****Regulations**

21 CFR, Cum. Supp., 2.100

**Pertinent 1906 Act Decisions**

United States v. Lesser, et al.  
66 F. 2d 612 (C.C.A. 2, 1933)  
United States v. 5 One-Pint Bottles \* \* \* Elixir Terpin Hydrate and Codeine  
9 F. Supp. 990 (S.D. N.Y., 1934)  
United States v. King & Howe, Inc., et al.  
78 F. 2d 693 (C.C.A. 2, 1935)  
United States v. William H. Rorer, Inc.  
27 F. Supp. 671 (E.D. Pa., 1936)  
Strong, Cobb & Co., Inc. v. United States  
103 F. 2d 671 (C.C.A. 6, 1939)  
United States v. S. B. Penick & Co., et al.  
136 F. 2d 413 (C.C.A. 2, 1943)

**1938 Act Decisions**

United States v. Norman C. Heron (N. C. Heron Co.), page 253  
(S.D. Calif., 1940) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 345) Issued March 1942

**Trade Correspondence**

TC- 13, Dec. 1, 1939, page 574	TC-268, May 7, 1940, page 674
TC- 76, Feb. 19, 1940, page 601	TC-294, May 7, 1940, page 684
TC-115, Feb. 29, 1940, page 614	TC-370, July 9, 1941, page 718
TC-116, Feb. 29, 1940, page 614	TC-378, Dec. 29, 1941, page 722
TC-131, March 7, 1940, page 620	TC-383, May 4, 1942, page 724
TC-188, March 15, 1940, page 642	TC-398, Jan. 21, 1943, page 732
TC-228, April 11, 1940, page 659	

**Opinions of the Attorney General**

26 Ops. Att'y. Gen. 311, July 17, 1907  
26 Ops. Att'y. Gen. 546, March 27, 1908

**SECTION 501(c)****Pertinent 1906 Act Decisions**

United States v. 17 Bottles \* \* \* Labeled in Part "B & M"  
55 F. 2d 264 (D. Md., 1932)  
United States v. William H. Rorer, Inc.  
27 F. Supp. 671 (E.D. Pa., 1936)  
Strong, Cobb & Co., Inc. v. United States  
103 F. 2d 671 (C.C.A. 6, 1939)  
United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
32 F. Supp. 958 (S.D. N.Y., 1940)



## SECTION 501 (c)—continued

## 1938 Act Decisions

- United States v. Buffalo Pharmacal Co., Inc. et al., page 262  
 131 F. 2d 500 (C.C.A. 2, 1942)  
 United States v. 43½ Gross \* \* \* "Xcello's Prophylactics," et al., page 173  
 65 F. Supp. 534 (D. Minn., 1946)  
 United States v. Crown Rubber Sundries Co. et al., page 330  
 67 F. Supp. 92 (N.D. Ohio, 1946)  
 Gellman v. United States, page 205  
 159 F. 2d 881 (C.C.A. 8, 1947)  
 Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States,  
 page 370  
 169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)

## Trade Correspondence

- |              |                    |              |                   |
|--------------|--------------------|--------------|-------------------|
| TC-294, May  | 7, 1940, page 684  | TC-1-A, Nov. | 5, 1945, page 748 |
| TC-316, Aug. | 20, 1940, page 693 |              |                   |

## SECTION 502(a)

## Regulations

21 CFR, Cum. Supp., 2.101

## Pertinent 1906 Act Decisions

- United States v. Johnson  
 221 U.S. 488 (1911)  
 Dr. J. L. Stephens Co. v. United States  
 (C.C.A. 6, 1913) White and Gates, "Decisions of Courts in Cases Under  
 the Federal Food and Drugs Act," p. 471  
 United States v. American Laboratories  
 222 Fed. 104 (E.D. Pa., 1915)  
 Seven Cases of Eckman's Alternative v. United States  
 239 U.S. 510 (1916)  
 Eleven Gross Packages \* \* \* of Dr. Williams' Pink Pills v. United States  
 233 Fed. 71 (C.C.A. 3, 1916)  
 United States v. Tubercleicide Co.  
 252 Fed. 938 (S.D. Calif., 1916)  
 United States v. Natura Co.  
 250 Fed. 925 (N.D. Calif., 1917)  
 United States v. Pulmonol Chemical Co.  
 (E.D. N.Y., 1917) White and Gates, "Decisions of Courts in Cases Under  
 the Federal Food and Drugs Act," p. 806  
 Dr. J. H. McLean Medicine Co. v. United States  
 253 Fed. 694 (C.C.A. 8, 1918)  
 Bradley v. United States  
 264 Fed. 79 (C.C.A. 5, 1920)  
 Kar-Ru Chemical Co. v. United States  
 264 Fed. 921 (C.C.A. 9, 1920)  
 Hall v. United States  
 267 Fed. 795 (C.C.A. 5, 1920)  
 United States v. Eleven Packages of B. & M. External Remedy  
 (D. N.H., 1922) White and Gates, "Decisions of Courts in Cases Under  
 the Federal Food and Drugs Act," p. 1059  
 United States v. Chichester Chemical Co.  
 298 Fed. 829 (App. D.C., 1924)  
 Goodwin, et al. v. United States  
 2 F. 2d 200 (C.C.A. 6, 1924)  
 United States v. John J. Fulton Co.  
 33 F. 2d 506 (C.C.A. 9, 1929)  
 United States v. 23 7/12 Dozen Bottles \* \* \* "Lee's Save the Baby"  
 44 F. 2d 831 (D. Conn., 1930)



## SECTION 502 (a)—continued

- United States v. Ninety-Four Dozen \* \* \* Half-Gallon Bottles Capon Springs Water  
48 F. 2d 378 (E.D. Pa., 1930), affirmed 51 F. 2d 913 (C.C.A. 3)
- Chichester Chemical Co., et al. v. United States  
49 F. 2d 516 (App. D.C., 1931)
- United States v. 17 Bottles \* \* \* Labeled in Part "B. & M."  
55 F. 2d 264 (D. Md., 1932)
- United States v. Lesser, et al.  
66 F. 2d 612 (C.C.A. 2, 1933)
- George A. Breon & Co., Inc. v. United States  
74 F. 2d 4 (C.C.A. 8, 1934)
- United States v. 5 One-Pint Bottles \* \* \* Elixir Terpin Hydrate and Codeine  
9 F. Supp. 990 (S.D. N.Y., 1934)
- Taylor, et al. v. United States  
80 F. 2d 604 (C.C.A. 5, 1936), certiorari denied 297 U.S. 708 (1936)
- United States v. William H. Rorer, Inc.  
27 F. Supp. 671 (E.D. Pa., 1936)
- Alberty v. United States  
91 F. 2d 461 (C.C.A. 9, 1937)
- United States v. Dr. David Roberts Veterinary Co., Inc., et al.  
104 F. 2d 785 (C.C.A. 7, 1939)
- United States v. Lee  
107 F. 2d 522 (C.C.A. 7, 1939), certiorari denied 309 U.S. 659 (1940)
- United States v. Fifty-Nine Tubes \* \* \* of Lutein Tablets  
32 F. Supp. 958 (S.D. N.Y., 1940)
- United States v. S. B. Penick & Co., et al.  
136 F. 2d 413 (C.C.A. 2, 1943)

## 1938 Act Decisions

- United States v. Norman C. Heron (N. C. Heron Co.), page 253  
(S.D. Calif., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 345) Issued March 1942
- United States v. 32½ Cases of Merlek Mineral Water, page 2  
(D. Ariz., 1940) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 513) Issued September 1942
- United States v. 6 Devices, "Electreat Mechanical Heart," page 5  
38 F. Supp. 236 (W.D. Mo., 1941)
- United States v. 11¼ Dozen Packages \* \* \* "Mrs. Moffat's Shoo Fly Powders for Drunkenness," page 8  
40 F. Supp. 208 (W.D. N.Y., 1941)
- United States v. Lee, etc., page 443  
40 F. Supp. 801 (E.D. Wis., 1941)
- United States v. Research Laboratories, Inc., page 15  
126 F. 2d 42 (C.C.A. 9, 1942), certiorari denied 317 U.S. 656 (1942)
- United States v. Lee, etc., page 445  
131 F. 2d 464 (C.C.A. 7, 1942)
- United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
131 F. 2d 500 (C.C.A. 2, 1942)
- United States v. Fifteen Cartons \* \* \* Sekov Reducer, page 22  
45 F. Supp. 52 (S.D. Tex., 1942)
- Empire Oil & Gas Corporation, et al. v. United States, page 270  
136 F. 2d 868 (C.C.A. 9, 1943)
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. Howard-Iowa Products Co., page 274  
(S.D. Iowa, 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1010) Issued March 1945
- United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- United States v. 50¾ Dozen Bottles, More or Less, of "Sulfa-Seb," et al., page 94  
54 F. Supp. 759 (W.D. Mo., 1944)
- United States v. 62 Packages, More or Less, of Marmola Prescription Tablets, page 107  
142 F. 2d 107 (C.C.A. 7, 1944), certiorari denied 323 U.S. 731 (1944)
- United States v. 1 Dozen Bottles \* \* \* "Boncquet Tablets," page 122  
146 F. 2d 361 (C.C.A. 4, 1944)



## SECTION 502 (a)—continued

- United States v. 70½ Dozen Bottles \* \* \* "666," page 89  
(M.D. Ga., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1231) Issued June 1945
- Fred B. Collier and Diane J. Collier v. McNutt et al., page 493  
(D. of Col., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 2140) Issued April 1948
- United States v. Elmer J. Dailey (Dailey's Laboratories), page 299  
(S.D. Calif., 1944) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1326) Issued November 1945
- United States v. Five Cases \* \* \* "Capon Springs Water," page 141  
62 F. Supp. 736 (S.D. N.Y., 1945)
- United States v. 43½ Gross \* \* \* "Xcello's Rubber Prophylactics," et al., page 173  
65 F. Supp. 534 (D. Minn., 1946)
- United States v. Alberty, etc., page 315  
65 F. Supp. 945 (S.D. Calif., 1946)
- United States v. One Article of Device Labeled Spectro-Chrome et al., page 207  
66 F. Supp. 754 (D. Ore., 1946)
- United States v. Kordel, page 328  
66 F. Supp. 538 (N.D. Ill., 1946)
- United States v. Crown Rubber Sundries Co., et al., page 330  
67 F. Supp. 92 (N.D. Ohio, 1946)
- United States v. Five Cases \* \* \* "Capon Springs Water," page 187  
156 F. 2d 493 (C.C.A. 2, 1946)
- United States v. Six Dozen Bottles \* \* \* "Dr. Peter's Kuriko," page 197  
158 F. 2d 667 (C.C.A. 7, 1947)
- Alberty v. United States, page 332  
159 F. 2d 278 (C.C.A. 9, 1947)
- United States v. One Device, etc., "Tox Eliminator," etc., page 199  
160 F. 2d 194 (C.C.A. 10, 1947)
- Gellman v. United States, page 205  
159 F. 2d 881 (C.C.A. 8, 1947)
- United States v. Olsen, page 210  
161 F. 2d 669 (C.C.A. 9, 1947), certiorari denied 332 U.S. 768 (1947)
- United States v. Kordel, page 343  
164 F. 2d 913 (C.C.A. 7, 1947)
- Urbeteit v. United States, page 212  
164 F. 2d 245 (C.C.A. 5, 1947)
- United States v. 9 Bottles \* \* \* "Colusa Natural Oil," etc., page 218  
78 F. Supp. 721 (N.D. Iowa, 1947)
- United States v. Dinshah P. Ghadiali and Dinshah Spectro-Chrome Institute, page 365  
165 F. 2d 957 (C.C.A. 3, 1948), certiorari denied 334 U.S. 821 (1948)
- United States v. One Article of Device Labeled Spectro-Chrome, page 226  
77 F. Supp. 50 (D. Ore., 1948)
- Research Laboratories, Inc. v. United States, page 227  
167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948)
- United States v. Bess J. Levine, Trading as Miracle Food Co., page 367  
(E.D. Pa., 1948)
- Pasadena Research Laboratories, Inc., and Russell B. Bavouset v. United States, page 370  
169 F. 2d 375 (C.C.A. 9, 1948), certiorari denied 335 U.S. 853 (1948)
- United States v. Urbeteit, page 249  
335 U.S. 355 (1948)
- Kordel v. United States, page 382  
335 U.S. 345 (1948)
- United States v. Dr. Charles Kaadt and Dr. Peter S. Kaadt, page 388  
171 F. 2d 600 (C.A. 7, 1948)
- United States v. Two Articles of Device \* \* \* "Tox Eliminator," etc., page 529  
(E.D. Okla., 1949)
- United States v. Various Quantities of \* \* \* "Instant Alberty Food \* \* \*," etc., page 533  
83 F. Supp. 882 (D. of Col., 1949)



## SECTION 502(a)—continued

- Lafayette M. Gray (also known as L. M. Gray), Appellant v. United States,  
page 537  
174 F. 2d 919 (C.A. 8, 1949)  
United States v. Urbeteit etc., page 560  
336 U.S. 804 (1949)  
United States v. Four Devices, Labeled in Part "Color-Therm" etc., and Franklin  
D. Lee  
(C.A. 10, 1949)  
Colusa Remedy Co. v. United States  
(C.A. 8, 1949)  
Urbeteit v. United States  
(C.A. 5, 1949)

## Of Incidental Interest

- American School of Magnetic Healing v. McAnnulty  
187 U.S. 94 (1902)  
Donaldson v. Read Magazine, Inc., et al.  
333 U.S. 178 (1948)  
Pinkus v. Reilly  
170 F. 2d 786 (C.C.A. 3, 1948), certiorari granted May 16, 1949

## Trade Correspondence

- |                                  |                                  |
|----------------------------------|----------------------------------|
| TC- 13, Dec. 1, 1939, page 574   | TC-352, Jan. 22, 1941, page 709  |
| TC- 20, Feb. 9, 1940, page 580   | TC-354, Feb. 4, 1941, page 710   |
| TC-109, Feb. 29, 1940, page 612  | TC-355, Feb. 12, 1941, page 711  |
| TC-116, Feb. 29, 1940, page 614  | TC-357, April 17, 1941, page 712 |
| TC-129, March 7, 1940, page 620  | TC-360, April 24, 1941, page 713 |
| TC-190, March 15, 1940, page 642 | TC-364, July 7, 1941, page 716   |
| TC-191, March 15, 1940, page 643 | TC-376, Dec. 4, 1941, page 721   |
| TC-193, March 15, 1940, page 643 | TC-378, Dec. 29, 1941, page 722  |
| TC-208, March 21, 1940, page 650 | TC-380, Jan. 23, 1942, page 723  |
| TC-254, April 25, 1940, page 668 | TC-385, May 29, 1942, page 725   |
| TC-280, May 7, 1940, page 680    | TC-391, Aug. 21, 1942, page 728  |
| TC-287, May 7, 1940, page 681    | TC-392, Aug. 20, 1942, page 728  |
| TC-303, Aug. 20, 1940, page 688  | TC-397, Jan. 7, 1943, page 731   |
| TC-306, Aug. 20, 1940, page 689  | TC-398, Jan. 21, 1943, page 732  |
| TC-312, Aug. 20, 1940, page 691  | TC-401, April 19, 1943, page 734 |
| TC-313, Aug. 20, 1940, page 692  | TC-410, Dec. 1, 1943, page 738   |
| TC-316, Aug. 20, 1940, page 693  | TC-415, April 10, 1944, page 741 |
| TC-324, Sept. 5, 1940, page 697  | TC-419, Aug. 18, 1944, page 743  |
| TC-331, Sept. 5, 1940, page 700  | TC-422, Dec. 6, 1944, page 744   |
| TC-337, Sept. 5, 1940, page 702  | TC-424, Dec. 20, 1944, page 745  |
| TC-338, Sept. 5, 1940, page 703  | TC-430, June 27, 1945, page 747  |
| TC-343, Dec. 13, 1940, page 704  | TC-1-A, Nov. 5, 1945, page 748   |
| TC-348, Dec. 18, 1940, page 707  |                                  |

## Statements of General Policy or Interpretation

- 21 CFR 3.3, March 12, 1948, page 756

## Pertinent Federal Trade Commission Act Decisions

- Raladam Co. v. Federal Trade Commission  
42 F. 2d 430 (C.C.A. 6, 1930), affirmed on question of the Commission's  
jurisdiction, 283 U.S. 643 (1931)  
Federal Trade Commission v. American Snuff Co.  
38 F. 2d 547 (C.C.A. 3, 1930)  
E. Griffiths Hughes, Inc. v. Federal Trade Commission  
77 F. 2d 886 (C.C.A. 2, 1935), certiorari denied 296 U.S. 617 (1935)  
Fairyfoot Products Co. v. Federal Trade Commission  
80 F. 2d 684 (C.C.A. 7, 1935)  
Belmont Laboratories, Inc. v. Federal Trade Commission  
103 F. 2d 538 (C.C.A. 3, 1939)  
Justin Haynes & Company, Inc. v. Federal Trade Commission  
105 F. 2d 988 (C.C.A. 2, 1939), certiorari denied 308 U.S. 616 (1939)  
H. N. Heusner & Son v. Federal Trade Commission  
106 F. 2d 596 (C.C.A. 3, 1939)



## SECTION 502(a)—continued

- El Moro Cigar Company v. Federal Trade Commission  
107 F. 2d 429 (C.C.A. 4, 1939)
- Capon Water Company et al. v. Federal Trade Commission  
107 F. 2d 516 (C.C.A. 3, 1939)
- Dr. W. B. Caldwell, Inc. v. Federal Trade Commission  
111 F. 2d 889 (C.C.A. 7, 1940)
- Neff v. Federal Trade Commission  
117 F. 2d 495 (C.C.A. 4, 1941)
- Alberty v. Federal Trade Commission  
118 F. 2d 669 (C.C.A. 9, 1941), certiorari denied 314 U.S. 630 (1941)
- D. D. D. Corporation v. Federal Trade Commission  
125 F. 2d 679 (C.C.A. 7, 1942)
- John J. Fulton Co. v. Federal Trade Commission  
130 F. 2d 85 (C.C.A. 9, 1942), certiorari denied 317 U.S. 679 (1942)
- Stanton v. Federal Trade Commission  
131 F. 2d 105 (C.C.A. 10, 1942)
- Earl Aronberg, trading as Positive Products Company and Rex Products Company v. Federal Trade Commission  
132 F. 2d 165 (C.C.A. 7, 1942)
- Bockenstelle et al. v. Federal Trade Commission  
134 F. 2d 369 (C.C.A. 10, 1943)
- Sebrone Co., et al. v. Federal Trade Commission  
135 F. 2d 676 (C.C.A. 7, 1943)
- American Medicinal Products, Inc., et al. v. Federal Trade Commission  
136 F. 2d 426 (C.C.A. 9, 1943)
- Phillip R. Park, Inc. v. Federal Trade Commission  
136 F. 2d 428 (C.C.A. 9, 1943)
- Stanley Laboratories, Inc. et al. v. Federal Trade Commission  
138 F. 2d 388 (C.C.A. 9, 1943)
- Miles Laboratories, Inc. v. Federal Trade Commission  
140 F. 2d 683 (App. D.C., 1944), certiorari denied 322 U.S. 752 (1944)
- Irwin et al. v. Federal Trade Commission  
143 F. 2d 316 (C.C.A. 8, 1944)
- Ultra-Violet Products, Inc. v. Federal Trade Commission  
143 F. 2d 814 (C.C.A. 9, 1944)
- J. E. Todd, Inc. v. Federal Trade Commission  
145 F. 2d 858 (App. D.C., 1944)
- Lekas & Drivas, Inc. v. Federal Trade Commission  
145 F. 2d 976 (C.C.A. 2, 1944)
- A. P. W. Paper Co., Inc. v. Federal Trade Commission  
149 F. 2d 424 (C.C.A. 2, 1945)
- Gulf Oil Corporation v. Federal Trade Commission  
150 F. 2d 106 (C.C.A. 5, 1945)
- Associated Laboratories, Inc. v. Federal Trade Commission  
150 F. 2d 629 (C.C.A. 2, 1945)
- Carlay Co. et al. v. Federal Trade Commission  
153 F. 2d 493 (C.C.A. 7, 1946)
- Jacob Siegal Company v. Federal Trade Commission  
327 U.S. 608 (1946)
- Federal Trade Commission v. A. P. W. Paper Co., Inc.  
328 U.S. 193 (1946)

## Opinions of Attorney General

26 Ops. Att'y. Gen. 546, March 27, 1908

## SECTION 502(b)

## Regulations

21 CFR, Cum. Supp., 2.102

## 1938 Act Decisions

United States v. Elmer J. Dailey (Dailey's Laboratories), page 299  
(S.D. Calif., 1944) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Drugs and Devices (No. 1326) Issued November  
1945



## SECTION 502(b)—continued

## Trade Correspondence

TC- 17, Feb. 9, 1940, page 579	TC-187, March 15, 1940, page 641
TC- 41, Feb. 12, 1940, page 585	TC-254, April 25, 1940, page 668
TC- 86, Feb. 21, 1940, page 605	TC-269, May 7, 1940, page 675
TC-100, Feb. 21, 1940, page 609	TC-302, Aug. 20, 1940, page 687
TC-107, Feb. 29, 1940, page 611	TC-314, Aug. 20, 1940, page 692
TC-116, Feb. 29, 1940, page 614	TC-331, Sept. 5, 1940, page 700
TC-160, March 14, 1940, page 631	TC-365, July 7, 1941, page 716
TC-174, March 14, 1940, page 637	

## SECTION 502(c)

## Regulations

21 CFR, Cum. Supp., 2.103

## Trade Correspondence

TC-100, Feb. 21, 1940, page 609	TC-316, Aug. 20, 1940, page 693
TC-181, March 15, 1940, page 639	TC-423, Dec. 18, 1944, page 744
TC-310, Aug. 20, 1940, page 690	

## SECTION 502(d)

## Regulations

21 CFR, Cum. Supp., 2.104

21 CFR, Cum. Supp., 145.1, 7 F.R. 460

## Pertinent 1906 Act Decisions

United States of America v. Antikamnia Chemical Company  
231 U.S. 654 (1914)

United States v. 5 One-Pint Bottles \* \* \* Elixir Terpin Hydrate and Codeine  
9 F. Supp. 990 (S.D. N.Y., 1934)

## Trade Correspondence

TC- 29, Feb. 9, 1940, page 582	TC-267, May 7, 1940, page 674
TC- 56, Feb. 12, 1940, page 591	TC-357, April 17, 1941, page 712
TC-116, Feb. 29, 1940, page 614	TC-385, May 29, 1942, page 725
TC-174, March 14, 1940, page 637	

## SECTION 502(e)

## Regulations

21 CFR, Cum. Supp., 2.105

## Pertinent 1906 Act Decisions

Armour v. Wanamaker

202 Fed. 423 (C.C.A. 3, 1913)

United States v. Eleven Cartons of \* \* \* "Vapex"

59 F. 2d 446 (D. Md., 1932)

Strong, Cobb & Co., Inc. v. United States

103 F. 2d 671 (C.C.A. 6, 1939)

## 1938 Act Decisions

United States v. Lee, etc., page 443

40 F. Supp. 801 (E.D. Wis., 1941)



## SECTION 502(e)—continued

Arner Co., Inc., et al. v. United States, page 99

142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)

United States v. Crescent-Kelvan Company et al., page 359

164 F. 2d 582 (C.C.A. 3, 1948)

Lafayette M. Gray (also known as L. M. Gray), Appellant v. United States, page 537

174 F. 2d 919 (C.A. 8, 1949)

## Trade Correspondence

TC- 25, Feb. 9, 1940, page 581

TC- 34, Feb. 9, 1940, page 584

TC- 46, Feb. 12, 1940, page 587

TC- 75, Feb. 19, 1940, page 601

TC-116, Feb. 29, 1940, page 614

TC-117, Feb. 29, 1940, page 615

TC-122, Feb. 29, 1940, page 617

TC-123, Feb. 29, 1940, page 618

TC-140, March 7, 1940, page 623

TC-174, March 14, 1940, page 637

TC-189, March 15, 1940, page 642

TC-190, March 15, 1940, page 642

TC-191, March 15, 1940, page 643

TC-196, March 15, 1940, page 645

TC-267, May 7, 1940, page 674

TC-270, Aug. 20, 1940, page 675

TC-314, Aug. 20, 1940, page 692

TC-319, Aug. 20, 1940, page 694

TC-324, Sept. 5, 1940, page 697

TC-327, Sept. 5, 1940, page 698

TC-328, Sept. 5, 1940, page 699

TC-355, Feb. 12, 1941, page 711

TC-357, April 17, 1941, page 712

TC-368, July 9, 1941, page 717

TC-385, May 29, 1942, page 725

TC-396, Dec. 21, 1942, page 731

TC-419, Aug. 18, 1944, page 743

## Opinions of the Attorney General

27 Ops. Att'y. Gen. 143, January 15, 1909

## SECTION 502(f)

## Regulations

21 CFR, 1944 Supp., 2.106, 9 F.R. 12255

21 CFR, 1946 Supp., 2.106, 11 F.R. 12841

## 1938 Act Decisions

Sekov Corporation v. United States, page 53

139 F. 2d 197 (C.C.A. 5, 1943)

United States v. 50¾ Dozen Bottles, More or Less, of Sulfa-Seb et al., page 94

54 F. Supp. 759 (W.D. Mo., 1944)

United States v. 150 Packages, etc., Labeled in Part Bush Mulso Tablets et al.

83 F. Supp. 875 (E.D. Mo., 1947)

United States v. Colgrove et al.

83 F. Supp. 880 (S.D. Calif., 1947)

United States v. Sullivan, page 350

332 U.S. 689 (1948)

United States v. Two Articles of Device \* \* \* "Tox Eliminator," etc., page 529  
(E.D. Okla., 1949)

United States v. Various Quantities of "Instant Alberty Food \* \* \*," etc., page 533

83 F. Supp. 882 (D. of Col., 1949)

Lafayette M. Gray (also known as L. M. Gray), Appellant v. United States, page 537

174 F. 2d 919 (C.A. 8, 1949)

Colgrove, etc. and Colusa Remedy Co. v. United States  
(C.A. 9, 1949)



## SECTION 502(f)—continued

## Trade Correspondence

TC- 14, Nov. 1, 1940, page 574	TC-373, Aug. 26, 1941, page 719
TC- 54, Feb. 12, 1940, page 590	TC-375, Dec. 10, 1941, page 720
TC- 55, Feb. 12, 1940, page 591	TC-382, Jan. 23, 1942, page 724
TC- 84, Feb. 21, 1940, page 604	TC-386, May 29, 1942, page 725
TC- 85, Feb. 21, 1940, page 604	TC-390, Aug. 17, 1942, page 727
TC- 98, Feb. 21, 1940, page 609	TC-391, Aug. 21, 1942, page 728
TC-100, Feb. 21, 1940, page 609	TC-393, Aug. 21, 1942, page 729
TC-116, Feb. 29, 1940, page 614	TC-394, Nov. 30, 1942, page 730
TC-160, March 14, 1940, page 631	TC-396, Dec. 21, 1942, page 731
TC-163, March 14, 1940, page 633	TC-397, Jan. 7, 1943, page 731
TC-164, March 14, 1940, page 633	TC-399, Jan. 21, 1943, page 733
TC-181, March 15, 1940, page 639	TC-400, April 7, 1943, page 733
TC-193, March 15, 1940, page 643	TC-404, July 13, 1943, page 735
TC-231, April 11, 1940, page 659	TC-413, Feb. 24, 1944, page 741
TC-310, Aug. 20, 1940, page 690	TC-414, April 10, 1944, page 741
TC-312, Aug. 20, 1940, page 691	TC-415, April 10, 1944, page 741
TC-316, Aug. 20, 1940, page 693	TC-417, May 29, 1944, page 742
TC-323, Sept. 5, 1940, page 696	TC-418, July 12, 1944, page 742
TC-326, Sept. 5, 1940, page 698	TC-420, Nov. 3, 1944, page 743
TC-330, Sept. 5, 1940, page 699	TC-421, Nov. 10, 1944, page 743
TC-333, Sept. 5, 1940, page 700	TC-422, Dec. 6, 1944, page 744
TC-337, Sept. 5, 1940, page 702	TC-423, Dec. 18, 1944, page 744
TC-350, Jan. 9, 1941, page 708	TC-424, Dec. 20, 1944, page 745
TC-351, Jan. 24, 1941, page 709	TC-425, Jan. 5, 1945, page 745
TC-355, Feb. 12, 1941, page 711	TC-426, Jan. 22, 1945, page 746
TC-356, Feb. 12, 1941, page 711	TC-429, May 21, 1945, page 747
TC-361, April 24, 1941, page 713	TC-430, June 27, 1945, page 747
TC-362, July 7, 1941, page 714	TC-431, Aug. 10, 1945, page 747
TC-366, July 7, 1941, page 716	TC-4-A, Nov. 5, 1945, page 750
TC-367, July 9, 1941, page 717	TC-6-A, Feb. 14, 1946, page 752
TC-371, July 9, 1941, page 718	TC-7-A, March 12, 1946, page 752
TC-372, July 9, 1941, page 719	

## Statements of General Policy or Interpretation

21 CFR 3.3, March 12, 1948, page 756  
 21 CFR 3.4, March 12, 1948, page 757

## SECTION 502(g)

## 1938 Act Decisions

United States v. Buffalo Pharmacal Co., Inc., et al., page 262  
 131 F. 2d 500 (C.C.A. 2, 1942)

## Trade Correspondence

TC-116, Feb. 29, 1940, page 614 TC-375, Dec. 10, 1941, page 720

## Statements of General Policy or Interpretation

21 CFR 3.5, March 12, 1948, page 757

## SECTION 502(i)

## Trade Correspondence

TC- 23, Feb. 9, 1940, page 580 TC-100, Feb. 21, 1940, page 609



## SECTION 502(j)

## 1938 Act Decisions

- United States v. 11¼ Dozen Packages \* \* \* "Mrs. Moffat's Shoo Fly Powders for Drunkenness," page 8  
40 F. Supp. 208 (W.D. N.Y., 1941)
- United States v. Fifteen Cartons \* \* \* Sekov Reducer, page 22  
45 F. Supp. 52 (S.D. Tex., 1942)
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- Sekov Corporation v. United States, page 53  
139 F. 2d 197 (C.C.A. 5, 1943)
- United States v. Sekov Corporation and Hazel Ruth Vokes (Sekov Studios), page 448  
(S.D. Calif., 1943) Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices (No. 1001) Issued March 1945
- United States v. 62 Packages \* \* \* Marmola Prescription Tablets et al., page 107  
142 F. 2d 107 (C.C.A. 7, 1944), certiorari denied 323 U.S. 731 (1944)

## Trade Correspondence

- |                                  |                                  |
|----------------------------------|----------------------------------|
| TC- 1, Aug. 26, 1938, page 561   | TC-356, Feb. 12, 1941, page 711  |
| TC- 2, Sept. 8, 1938, page 561   | TC-360, April 24, 1941, page 713 |
| TC- 3, Sept. 8, 1938, page 562   | TC-366, July 7, 1941, page 716   |
| TC- 4, undated, page 562         | TC-372, July 9, 1941, page 719   |
| TC- 9, May 13, 1939, page 565    | TC-373, Aug. 26, 1941, page 719  |
| TC- 78, undated, page 602        | TC-389, Aug. 6, 1942, page 727   |
| TC- 82, Feb. 21, 1940, page 604  | TC-390, Aug. 17, 1942, page 727  |
| TC-113, Feb. 29, 1940, page 613  | TC-393, Aug. 21, 1942, page 729  |
| TC-163, March 14, 1940, page 633 | TC-394, Nov. 30, 1942, page 730  |
| TC-164, March 14, 1940, page 633 | TC-400, April 7, 1943, page 733  |
| TC-165, March 14, 1940, page 633 | TC-414, April 10, 1944, page 741 |
| TC-186, March 15, 1940, page 641 | TC-417, May 29, 1944, page 742   |
| TC-227, April 11, 1940, page 658 | TC-418, July 12, 1944, page 742  |
| TC-301, July 2, 1940, page 687   | TC-421, Nov. 10, 1944, page 743  |
| TC-326, Sept. 5, 1940, page 698  | TC-425, Jan. 5, 1945, page 745   |
| TC-333, Sept. 5, 1940, page 700  | TC-431, Aug. 10, 1945, page 747  |
| TC-350, Jan. 9, 1941, page 708   | TC-4-A, Nov. 5, 1945, page 750   |

## Statements of General Policy or Interpretation

21 CFR 3.4, March 12, 1948, page 757

## Pertinent Federal Trade Commission Act Decisions

- Earl Aronberg, trading as Positive Products Company and Rex Products Co. v. Federal Trade Commission  
132 F. 2d 165 (C.C.A. 7, 1942)
- American Medicinal Products, Inc. et al. v. Federal Trade Commission  
136 F. 2d 426 (C.C.A. 9, 1943)

## SECTION 502(k)

## Regulations

21 CFR, Cum. Supp., 2.115

## SECTION 503(a)

## Regulations

21 CFR, Cum. Supp., 2.107  
21 CFR, 1945 Supp., 2.107, 10 F.R. 14176



## SECTION 503(a)—continued

## Pertinent 1906 Act Decisions

Strong, Cobb & Co., Inc. v. United States  
103 F. 2d 671 (C.C.A. 6, 1939)

## 1938 Act Decisions

Arner Co., Inc., et al. v. United States, page 99  
142 F. 2d 730 (C.C.A. 1, 1944), certiorari denied 323 U.S. 730 (1944)  
United States v. Sullivan, page 350  
332 U.S. 689 (1948)

## Trade Correspondence

TC-116, Feb. 29, 1940, page 614 TC-409, Sept. 18, 1943, page 738  
TC-369, July 9, 1941, page 718

## Statements of General Policy or Interpretation

21 CFR 3.7, November 30, 1948, page 759

## SECTION 503(b)

## Trade Correspondence

TC- 54, Feb. 12, 1940, page 590 TC-330, Sept. 5, 1940, page 699  
TC- 83, Feb. 21, 1940, page 604 TC-6-A, Feb. 14, 1946, page 752  
TC-174, March 14, 1940, page 637

## SECTION 504

## Regulations

Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.  
21 CFR, Cum. Supp., 135.01 *et seq.*, as amended, 21 CFR, 1946 Supp., 135.15.

## Trade Correspondence

TC-128, March 7, 1940, page 619 TC-251, April 25, 1940, page 667

## SECTION 505(a)

## Regulations

21 CFR, Cum. Supp., 2.109, as amended, 12 F.R. 408  
13 F.R. 6555

## 1938 Act Decisions

Martin Coughlin (Diamonex Co.) v. Federal Security Administrator, page 436

(N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of  
Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug,  
and Cosmetic Act (No. 7) Issued July 1946

## Trade Correspondence

TC- 78, undated, page 602 TC-414, April 10, 1944, page 741  
TC- 95, Feb. 21, 1940, page 608 TC-4-A, Nov. 5, 1945, page 750  
TC-113, Feb. 29, 1940, page 613



**SECTION 505(b)****Regulations**

21 CFR, Cum. Supp., 2.110

21 CFR, 1944 Supp., 2.110(b) and (d), 9 F.R. 12256

**1938 Act Decisions**

Martin Coughlin (Diamonex Co.) v. Federal Security Administrator, page 436  
 (N.D. Ill., 1946) Notices of Judgment Summarizing Judicial Review of  
 Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug,  
 and Cosmetic Act (No. 7) July 1946

**Trade Correspondence**

TC- 78, undated, page 602

TC-4-A, Nov. 5, 1945, page 750

TC- 95, Feb. 21, 1940, page 608

**SECTION 505(c)****Regulations**

21 CFR, Cum. Supp., 2.111

**1938 Act Decisions**

Martin Coughlin (Diamonex Co.) v. Federal Security Administrator, page 436  
 (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of  
 Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug,  
 and Cosmetic Act (No. 7) Issued July 1946

**SECTION 505(d)****Regulations**

21 CFR, 1944 Supp., 2.112, 9 F.R. 12256

**1938 Act Decisions**

Martin Coughlin (Diamonex Co.) v. Federal Security Administrator, page 436  
 (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of  
 Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug,  
 and Cosmetic Act (No. 7) Issued July 1946

**Trade Correspondence**

TC- 95, Feb. 21, 1940, page 608

**SECTION 505(e)****Regulations**

21 CFR, 1944 Supp., 2.113, 9 F.R. 12257

**SECTION 505(h)****1938 Act Decisions**

Martin Coughlin (Diamonex Co.) v. Federal Security Administrator, page 436  
 (N.D. Ill., 1944) Notices of Judgment Summarizing Judicial Review of  
 Orders Under Sections 701(f) and 505(h) of the Federal Food, Drug,  
 and Cosmetic Act (No. 7) Issued July 1946



## SECTION 505(i)

## Regulations

21 CFR, Cum. Supp., 2.114  
13 F.R. 6555

---

## SECTION 506(a)

## Regulations (Insulin)

12 F.R. 2226-2231, 8773, 14 F.R. 3374

---

## SECTION 507(a)

## Regulations (Penicillin-Streptomycin)

12 F.R. 2215, 2217-2226, 2231-2248	13 F.R. 3969
12 F.R. 2745-2746	13 F.R. 4186
12 F.R. 4023	13 F.R. 4315
12 F.R. 4369	13 F.R. 5152
12 F.R. 4961-4962	13 F.R. 5312
12 F.R. 5039	13 F.R. 5566
12 F.R. 5301	13 F.R. 5824
12 F.R. 5586	13 F.R. 6015
12 F.R. 6109	13 F.R. 6316
12 F.R. 6401	13 F.R. 6749
12 F.R. 7997-7998	13 F.R. 8386
12 F.R. 8151-8152	13 F.R. 8736
12 F.R. 8723	14 F.R. 886
13 F.R. 436-440	14 F.R. 1518
13 F.R. 589-590	14 F.R. 2136, 2137
13 F.R. 1087-1088	14 F.R. 2380
13 F.R. 1305	14 F.R. 2544
13 F.R. 1899-1901	14 F.R. 3262
13 F.R. 2291	14 F.R. 3263
13 F.R. 2414	14 F.R. 3493
13 F.R. 2475	14 F.R. 4871
13 F.R. 2950	14 F.R. 5006
13 F.R. 3252	14 F.R. 5189

## Statement of General Policy or Interpretation

21 CFR 3.8, January 12, 1949, page 759

---

## SECTION 601(a)

## Regulations

21 CFR, Cum. Supp., 2.200

## 1938 Act Decisions

United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 149  
59 F. Supp. 284, (W.D. La., 1945)  
United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 159  
61 F. Supp. 847 (W.D. La., 1945)  
United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 161  
61 F. Supp. 850 (W.D. La., 1945)  
Byrd v. United States, page 177  
154 F. 2d 62 (C.C.A. 5, 1946)



**SECTION 601(a)—continued****Trade Correspondence**

TC- 5, Oct. 17, 1938, page 563	TC-103, Feb. 29, 1940, page 610
TC- 6, Nov. 8, 1938, page 564	TC-170, March 14, 1940, page 635
TC- 9, May 13, 1939, page 565	TC-249, April 25, 1940, page 666
TC- 27, Feb. 9, 1940, page 581	TC-402, May 14, 1943, page 734
TC-102, Feb. 29, 1940, page 610	TC-412, Feb. 11, 1944, page 740

**Pertinent Federal Trade Commission Act Decisions**

Gelb et al. v. Federal Trade Commission  
144 F. 2d 580 (C.C.A. 2, 1944)  
Dearborn Supply Co. v. Federal Trade Commission  
146 F. 2d 5 (C.C.A. 7, 1944)

**SECTION 601(e)****1938 Act Decisions**

United States v. 3 7/12 Dozen Packages of Nu-Channe Perfected Brow Tint,  
page 149  
59 F. Supp. 284 (W.D. La., 1945)  
United States v. 3 7/12 Dozen Packages of Nu-Channe Perfected Brow Tint,  
page 159  
61 F. Supp. 847 (W.D. La., 1945)  
United States v. 3 7/12 Dozen Packages of Nu-Channe Perfected Brow Tint,  
page 161  
61 F. Supp. 850 (W.D. La., 1945)  
Byrd v. United States, page 177  
154 F. 2d 62 (C.C.A. 5, 1946)

**Trade Correspondence**

TC-249, April 25, 1940, page 666 TC-334, Sept. 5, 1940, page 701

**SECTION 602(a)****Regulations**

21 CFR, Cum. Supp., 2.201

**1938 Act Decisions**

United States v. Pinand, Inc., page 526  
(S.D. N.Y., 1947) Notices of Judgment Under the Federal Food, Drug,  
and Cosmetic Act, Cosmetics (No. 152) Issued February 1949

**Trade Correspondence**

TC- 10, Aug. 2, 1939, page 566 TC-243, April 25, 1940, page 665  
TC-153, March 7, 1940, page 628 TC-349, Dec. 28, 1940, page 707

**Pertinent Federal Trade Commission Act Decisions**

Proctor & Gamble Co. et al. v. Federal Trade Commission  
11 F. 2d 47 (C.C.A. 6, 1926), certiorari denied 273 U.S. 717 (1926)  
James S. Kirk & Co. et al. v. Federal Trade Commission  
59 F. 2d 179 (C.C.A. 7, 1932), certiorari denied 287 U.S. 663 (1932)  
Allen B. Wrisley Company et al. v. Federal Trade Commission  
113 F. 2d 437 (C.C.A. 7, 1940)  
Etablissements Rigaud, Inc. et al. v. Federal Trade Commission  
125 F. 2d 590 (C.C.A. 2, 1942)  
Houbigant, Inc. et al. v. Federal Trade Commission  
139 F. 2d 1019 (C.C.A. 2, 1944), certiorari denied 323 U.S. 763 (1944)



SECTION 602(a)—continued

Gelb et al. v. Federal Trade Commission

144 F. 2d 580 (C.C.A. 2, 1944)

Charles of the Ritz Distributors Corporation v. Federal Trade Commission

143 F. 2d 676 (C.C.A. 2, 1944)

SECTION 602(b)

Regulations

21 CFR, Cum. Supp., 2.202

Trade Correspondence

TC- 22, Feb. 9, 1940, page 580

TC-253, April 25, 1940, page 668

TC-244, April 25, 1940, page 665

SECTION 602(c)

Regulations

21 CFR, Cum. Supp., 2.203

Trade Correspondence

TC- 5, Oct. 17, 1938, page 563

SECTION 602(d)

Trade Correspondence

TC- 59, Feb. 15, 1940, page 592

SECTION 603

Regulations

21 CFR, Cum. Supp., 2.204

1938 Act Decisions

United States v. Sullivan, page 350

332 U.S. 689 (1948)

SECTION 604

Regulations

21 CFR, Cum. Supp., 135.01 *et seq.*, as amended 21 CFR, 1946 Supp., 135.15

Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3

1938 Act Decisions

United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 149

59 F. Supp. 284 (W.D. La., 1945)

United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 159

61 F. Supp. 847 (W.D. La., 1945)

United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 161

61 F. Supp. 850 (W.D. La., 1945)

Byrd v. United States, page 177

154 F. 2d 62 (C.C.A. 5, 1946)



## SECTION 604—continued

## Trade Correspondence

TC-249, April 25, 1940, page 666

TC-334, Sept. 5, 1940, page 701

## SECTION 701(a)

## Regulations

21 CFR, 1946 Supp. (subsequently decodified), 11 F.R. 177 A-541 (Organization and Procedures)

21 CFR, 1945 Supp., 196.1 10 F.R. 4789 (Disclosure of Official Information and Records)

21 CFR, Cum. Supp., 2.701 *et seq.*, 5 F.R. 2379 (Rules of Practice for Hearings) (Cf. the Administrative Procedure Act, 60 Stat. 237)

13 F.R. 6969

13 F.R. 6983 (Organization, Functions, Procedures, etc., of the Food and Drug Administration)

## Pertinent 1906 Act Decisions

United States v. Antikamnia Chemical Company  
231 U.S. 654 (1914)

## 1938 Act Decisions

United States v. 62 Packages \* \* \* Marmola Prescription Tablets et al., page 34  
48 F. Supp. 878 (W.D. Wis., 1943)United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)

## Opinions of the Attorney General

27 Ops. Att'y. Gen. 143, January 15, 1909

29 Ops. Att'y Gen. 494, July 8, 1912

40 Ops. Att'y Gen., Op. No. 6, March 12, 1941

## Statements of General Policy or Interpretation

21 CFR 3.10, May 20, 1949, page 762

## SECTION 701(b)

## Regulations

See references given under Section 801(b)

## SECTION 701(c)

## 1938 Act Decisions

Twin City Milk Producers Ass'n. et al. v. McNutt et al., page 398  
122 F. 2d 564 (C.C.A. 8, 1941)Willapoint Oysters, Inc. v. Ewing, et al., page 543  
174 F. 2d 676 (C.A. 9, 1949)

## SECTION 701(e)

## Pertinent 1906 Act Decisions

United States ex rel. Alsop Process Company v. Wilson  
33 App. D.C. 472 (1909)



## SECTION 701(e)—continued

## 1938 Act Decisions

- A. E. Staley Mfg. Co. v. Secretary of Agriculture et al., page 395  
120 F. 2d 258 (C.C.A. 7, 1941)
- Twin City Milk Producers Ass'n. et al. v. McNutt et al., page 398  
122 F. 2d 564 (C.C.A. 8, 1941)
- Twin City Milk Producers Ass'n. v. McNutt et al., page 403  
123 F. 2d 396 (C.C.A. 8, 1941)
- Quaker Oats Co. v. Federal Security Administrator, page 405  
129 F. 2d 76 (C.C.A. 7, 1942)
- Land O'Lakes Creameries, Inc., et al. v. McNutt et al., page 412  
132 F. 2d 653 (C.C.A. 8, 1943)
- Federal Security Administrator v. Quaker Oats Co., page 419  
318 U.S. 218 (1943)
- Columbia Cheese Co. et al. v. McNutt, page 426  
137 F. 2d 576 (C.C.A. 2, 1943), certiorari denied 321 U.S. 777 (1944)
- United States Cane Sugar Refiners' Ass'n. et al. v. McNutt, page 431  
138 F. 2d 116 (C.C.A. 2, 1943)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 149  
59 F. Supp. 284 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 159  
61 F. Supp. 847 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 161  
61 F. Supp. 850 (W.D. La., 1945)
- Byrd v. United States, page 177  
154 F. 2d 62 (C.C.A. 5, 1946)
- American Lecithin Co., Inc. v. McNutt, page 438  
155 F. 2d 784 (C.C.A. 2, 1946), certiorari denied 329 U.S. 763 (1946)
- Washington State Apple Advertising Commission et al. v. Federal Security  
Administrator, page 440  
156 F. 2d 589 (C.C.A. 9, 1946)
- Cook Chocolate Co. v. Miller et al., page 509  
72 F. Supp. 573 (D. of Col., 1947)
- Willapoint Oysters, Inc. v. Ewing et al., page 543  
174 F. 2d 676 (C.A. 9, 1949)

## Trade Correspondence

- |                                  |                                 |
|----------------------------------|---------------------------------|
| TC- 67, Feb. 15, 1940, page 597  | TC-325, Sept. 5, 1940, page 697 |
| TC-207, March 21, 1940, page 649 | TC-341, Oct. 28, 1940, page 704 |
| TC-305, Aug. 20, 1940, page 688  |                                 |

## Opinions of the Attorney General

- 40 Ops. Att'y. Gen., Op. No. 6, March 12, 1941

## SECTION 701(f)

## Pertinent 1906 Act Decisions

- Morgan et al. v. Nolan, United States Attorney  
3 F. Supp. 143 (S.D. Ind., 1933)
- Nolan, United States Attorney v. Morgan et al.  
69 F. 2d 471 (C.C.A. 7, 1934)

## 1938 Act Decisions

- A. E. Staley Mfg. Co. v. Secretary of Agriculture et al., page 395  
120 F. 2d 258 (C.C.A. 7, 1941)
- Twin City Milk Producers Ass'n. et al. v. McNutt et al., page 398  
122 F. 2d 564 (C.C.A. 8, 1941)



## SECTION 701(f)—continued

- Twin City Milk Producers Ass'n. v. McNutt et al., page 403  
123 F. 2d 396 (C.C.A. 8, 1941)
- Quaker Oats Co. v. Federal Security Administrator, page 405  
129 F. 2d 76 (C.C.A. 7, 1942)
- Land O' Lakes Creameries, Inc., et al. v. McNutt et al., page 412  
132 F. 2d 653 (C.C.A. 8, 1943)
- Federal Security Administrator v. Quaker Oats Co., page 419  
318 U.S. 218 (1943)
- Columbia Cheese Co. et al. v. McNutt, page 426  
137 F. 2d 576 (C.C.A. 2, 1943), certiorari denied 321 U.S. 777 (1944)
- United States Cane Sugar Refiners' Ass'n. et al. v. McNutt, page 431  
138 F. 2d 116 (C.C.A. 2, 1943)
- United States v. 306 Cases \* \* \* "Sandford Tomato Catsup With Preservative,"  
page 115  
55 F. Supp. 725 (E.D. N.Y., 1944)
- United States v. Lord-Mott Co., Inc., page 289  
57 F. Supp. 128 (D. Md., 1944)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 149  
59 F. Supp. 284 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 159  
61 F. Supp. 847 (W.D. La., 1945)
- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 161  
61 F. Supp. 850 (W.D. La., 1945)
- Byrd v. United States, page 177  
154 F. 2d 62 (C.C.A. 5, 1946)
- American Lecithin Co., Inc. v. McNutt, page 438  
155 F. 2d 784 (C.C.A. 2, 1946), certiorari denied 329 U.S. 763 (1946)
- Washington State Apple Advertising Commission et al. v. Federal Security  
Administrator, page 440  
156 F. 2d 589 (C.C.A. 9, 1946)
- Willapoint Oysters, Inc. v. Ewing et al., page 543  
174 F. 2d 676 (C.A. 9, 1949)

## Of Incidental Interest

- Barnard et al. v. Carey  
60 F. Supp. 539 (N.D. Ohio, 1945)
- Butler v. Kavanagh  
64 F. Supp. 741 (E.D. Mich., 1945), affirmed 156 F. 2d 158 (C.C.A. 6)

## SECTION 701(g)

## 1938 Act Decisions

- United States v. 3 7/12 Dozen Packages of Nu-Charme Perfected Brow Tint,  
page 149  
59 F. Supp. 284 (W.D. La., 1945)

## SECTION 702(a)

## Regulations

See references given under Section 902(a)

## 1938 Act Decisions

- Research Laboratories, Inc. v. United States, page 227  
167 F. 2d 410 (C.C.A. 9, 1948), certiorari denied 335 U.S. 843 (1948)

## Opinions of the Attorney General

- 27 Ops. Att'y. Gen. 300, April 14, 1909



**SECTION 702(b)****Regulations**

21 CFR, Cum. Supp., 2.700

**1938 Act Decisions**

United States v. 75 Cases \* \* \* Peanut Butter, page 82

54 F. Supp. 641 (D. Md., 1944)

Triangle Candy Co. et al. v. United States, page 294

144 F. 2d 195 (C.C.A. 9, 1944), 155 A.L.R. 903

United States v. 75 Cases \* \* \* Peanut Butter, etc., page 126

146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S. 856 (1945)

---

**SECTION 703****1938 Act Decisions**

United States v. 75 Cases \* \* \* Peanut Butter, page 82

54 F. Supp. 641 (D. Md., 1944)

United States v. 75 Cases \* \* \* Peanut Butter, page 126

146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S. 856 (1945)

United States v. Crescent-Kelvan Company et al., page 359

164 F. 2d 582 (C.C.A. 3, 1948)

**Trade Correspondence**

TC-304, Aug. 20, 1940, page 688

---

**SECTION 704****1938 Act Decisions**

United States v. 75 Cases \* \* \* Peanut Butter, etc., page 82

54 F. Supp. 641 (D. Md., 1944)

United States v. 75 Cases \* \* \* Peanut Butter, page 126

146 F. 2d 124 (C.C.A. 4, 1944), certiorari denied 325 U.S. 856 (1945)

United States v. Crescent-Kelvan Company et al., page 359

164 F. 2d 582 (C.C.A. 3, 1948)

United States v. Maryland Baking Company and Sara Piem, an individual, page 379

81 F. Supp. 560 (N.D. Ga., 1948)

---

**SECTION 706****Regulations**

21 CFR, Cum. Supp., 135.01 *et seq.*, as amended 21 CFR, 1946 Supp., 135.15

Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3

14 F.R. 3373

---

**SECTION 801(a)****Regulations**

13 F.R. 6749

**Pertinent 1906 Act Decisions**

Armbruster v. Mellon et al.

41 F. 2d 430 (App. D.C., 1930)

Knapp et al v. Callaway et al.

52 F. 2d 476 (S.D. N.Y., 1931)

United States v. King & Howe, Inc., et al.

78 F. 2d 693 (C.C.A. 2, 1935)



**SECTION 801(a)—continued****1938 Act Decisions**

The James J. Hill (Bowman v. Retzlaff et al.), page 496  
 65 F. Supp. 265 (D. Md., 1946)  
 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
 168 F. 2d 361 (C.C.A. 6, 1948)

**Trade Correspondence**

TC-121, Feb. 29, 1940, page 617 TC-192, March 15, 1940, page 643

**Opinions of the Attorney General**

25 Ops. Att'y. Gen. 62, October 2, 1903  
 25 Ops. Att'y. Gen. 142, April 19, 1904  
 25 Ops. Att'y. Gen. 244, September 2, 1904  
 26 Ops. Att'y. Gen. 311, July 17, 1907

**SECTION 801(b)****Regulations**

21 CFR, Cum. Supp., 2.300-2.312 (Governing imports)  
 13 F.R. 5117  
 13 F.R. 6749

**Pertinent 1906 Act Decisions**

United States v. King & Howe, Inc., et al.  
 78 F. 2d 693 (C.C.A. 2, 1935)

**1938 Act Decisions**

The James J. Hill (Bowman v. Retzlaff et al.), page 496  
 65 F. Supp. 265 (D. Md., 1946)  
 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
 168 F. 2d 361 (C.C.A. 6, 1948)

**Trade Correspondence**

TC-121, Feb. 29, 1940, page 617 TC-192, March 15, 1940, page 643

**Opinions of the Attorney General**

25 Ops. Att'y. Gen. 62, October 2, 1903  
 25 Ops. Att'y. Gen. 142, April 19, 1904  
 25 Ops. Att'y. Gen. 244, September 2, 1904  
 26 Ops. Att'y. Gen. 311, July 17, 1907

**SECTION 801(c)****Pertinent 1906 Act Decisions**

United States v. Acker, Merrall & Condit  
 133 Fed. 842 (S.D. N.Y., 1904)  
 Armbruster v. Mellon, et al.  
 41 F. 2d 430 (App. D.C., 1930)

**SECTION 801(d)****Pertinent 1906 Act Decisions**

United States v. Catz American Co.  
 53 F. 2d 425 (C.C.A. 9, 1931)



**SECTION 801(d)—continued****1938 Act Decisions**

- United States v. 215 Cases \* \* \* "Michigan Brand Grade A Tomato Catsup \* \* \*," page 513  
(E.D. N.Y., 1947)
- 230 Boxes, More or Less, of Fish et al. v. United States, page 238  
168 F. 2d 361 (C.C.A. 6, 1948)
- United States v. Kent Food Corporation and Clark-Iger Food Products Co., Inc.,  
page 242  
168 F. 2d 632 (C.C.A. 2, 1948), certiorari denied 335 U.S. 885 (1948)
- Stinson Canning Co. et al. v. United States, page 518  
170 F. 2d 764 (C.A. 4, 1948)

**Trade Correspondence**

- TC-192, March 15, 1940, page 643      TC-250, April 25, 1940, page 666

**SECTION 901****Pertinent 1906 Act Decisions**

- Shawnee Milling Co. v. Temple  
179 Fed. 517 (S.D. La., 1910)
- United States v. 420 Sacks of Flour  
180 Fed. 518 (E.D. La., 1910)
- Hipolite Egg Company v. United States  
220 U.S. 45 (1911)
- McDermott v. State of Wisconsin  
228 U.S. 115 (1913)
- United States v. Sweet Valley Wine Co.  
208 Fed. 85 (N.D. Ohio, 1913)
- Seven Cases of Eckman's Alterative v. United States of America  
239 U.S. 510 (1916)
- Weeks v. United States  
245 U.S. 618 (1918)
- United States v. The Merchants Biscuit Co.  
(D. Col., 1924) White and Gates, "Decisions of Courts in Cases Under  
the Federal Food and Drugs Act," p. 1129
- United States v. Eleven Cartons of \* \* \* "Vapex"  
59 F. 2d 446 (D. Md., 1932)
- United States v. Shreveport Grain & Elevator Co.  
287 U.S. 77 (1932)

**1938 Act Decisions**

- United States v. 62 Packages \* \* \* Marmola Prescription Tablets, page 34  
48 F. Supp. 878 (W.D. Wis., 1943)
- United States v. 7 Jugs, etc., "Dr. Salsbury's Rakos," etc., page 64  
53 F. Supp. 746 (D. Minn., 1944)
- United States v. Two Bags \* \* \* Poppy Seeds, page 135  
147 F. 2d 123 (C.C.A. 6, 1945)
- United States v. Sullivan, page 319  
67 F. Supp. 192 (M.D. Ga., 1946)
- United States v. Walsh, etc., page 337  
331 U.S. 432 (1947)

**SECTION 902(a)****Regulations**

On November 4, 1938, the Federal Security Administrator republished for codification purposes, with miscellaneous amendments, the regulations pertaining to sea-food inspection. This republication, published in 13 F.R. 6623, corrected in 13 F.R. 6683, contains no substantive revisions.



## SECTION 902(a)—continued

## Trade Correspondence

TC- 7, Feb. 28, 1939, page 564	TC-273, May 7, 1940, page 676
TC- 43, Feb. 12, 1940, page 586	TC-279, May 7, 1940, page 679
TC- 64, Feb. 12, 1940, page 596	TC-322, Sept. 5, 1940, page 696
TC- 66 Feb. 15, 1940, page 597	TC-346, Dec. 18, 1940, page 706
TC- 67, Feb. 15, 1940, page 597	TC-353, Jan. 24, 1941, page 710
TC-142, March 7, 1940, page 624	

---

## SECTION 902(b)

## Opinions of the Attorney General

26 Ops. Att'y. Gen. 50, September 27, 1906  
29 Ops. Att'y. Gen. 355, March 11, 1912  
30 Ops. Att'y. Gen. 164, May 24, 1913

---

## SECTION 902(c)

## Opinions of the Attorney General

26 Ops. Att'y. Gen. 166, February 3, 1907

---



# THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

As Amended

(Public—No. 717—Seventy-Fifth Congress, Chapter 675, Third Session, S. 5;  
52 Stat. 1040 *et seq.*)

## AN ACT<sup>1</sup>

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### CHAPTER I—SHORT TITLE

**Section 1.** This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

### CHAPTER II—DEFINITIONS

**Sec. 201.** For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Agency" means the Federal Security Agency.

(d) The term "Administrator" means the Federal Security Administrator.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

<sup>1</sup> The section numbers are those contained in the Act. Section 1 of the Act is Section 301 of Title 21 of the United States Code. To obtain the United States Code section number of any other section of the Act, remove the middle figure

(always a zero) of the statutory section number and insert the figure "3" before the remaining two numbers. For example, Section 201 of the Act becomes Section 321, Title 21, U.S.C.



(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

### CHAPTER III—PROHIBITED ACTS AND PENALTIES

#### Prohibited Acts

**Sec. 301.** The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received



in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, 506, 507, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

### Injunction Proceedings

**Sec. 302.** (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

### Penalties

**Sec. 303.** (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of



section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Administrator under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Administrator under this Act.

### Seizure

**Sec. 304.** (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.



(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Administrator, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

#### Hearing Before Report of Criminal Violation

**Sec. 305.** Before any violation of this Act is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

#### Report of Minor Violations

**Sec. 306.** Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

#### Proceedings in Name of United States; Provision as to Subpenas

**Sec. 307.** All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.



## CHAPTER IV—FOOD

## Definitions and Standards for Food

**Sec. 401.** Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Administrator shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Administrator for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

## Adulterated Food

**Sec. 402.** A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Administrator, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.



## Misbranded Food

**Sec. 403.** A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Administrator.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

## Emergency Permit Control

**Sec. 404.** (a) Whenever the Administrator finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or pack-



ing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Administrator as provided by such regulations.

(b) The Administrator is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Administrator shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Administrator shall have access to any factory or establishment, the operator of which holds a permit from the Administrator, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

#### Regulations Making Exemptions

**Sec. 405.** The Administrator shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

#### Tolerances for Poisonous Ingredients in Food and Certification of Coal-Tar Colors for Food

**Sec. 406.** (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Administrator shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Administrator shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.



Adulterated Drugs and Devices

**Sec. 501.** A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Administrator, insufficient for the making of such determination, the Administrator shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Administrator, are sufficient for purposes of this paragraph, then the Administrator shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

Misbranded Drugs and Devices

**Sec. 502.** A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.



(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Administrator. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Administrator to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Administrator shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Administrator shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506, and (2) such certificate or release is in effect with respect to such drug.

(1) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, aureomycin, chloramphenicol, or bacitracin, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).



**Exemptions in Case of Drugs and Devices**

**Sec. 503.** (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

- (1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and
- (2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502(b) and (c), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502(d).

**Certification of Coal-Tar Colors for Drugs**

**Sec. 504.** The Administrator shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

**New Drugs**

**Sec. 505.** (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Administrator an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Administrator as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Administrator may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Administrator by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Administrator deems necessary to enable him to study and investigate the application.

(d) If the Administrator finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Administrator pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application,



or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Administrator be suspended if the Administrator finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Administrator finds that the facts so require.

(g) Orders of the Administrator issued under this section shall be served (1) in person by any officer or employee of the Agency designated by the Administrator or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Administrator.

(h) An appeal may be taken by the applicant from an order of the Administrator refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Administrator be set aside. A copy of such petition shall be forthwith served upon the Administrator, or upon any officer designated by him for that purpose, and thereupon the Administrator shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Administrator shall be considered by the court unless such objection shall have been urged before the Administrator or unless there were reasonable grounds for failure so to do. The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence to be taken before the Administrator and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Administrator shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Administrator's order.

(i) The Administrator shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.



## Certification of Drugs Containing Insulin

**Sec. 506.** (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

(c) Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 501(b). The provisions of subsections (e), (f), and (g) of section 701 shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation.

Certification of Drugs Containing Penicillin, Streptomycin, Aureomycin,  
Chloramphenicol, or Bacitracin

**Sec. 507.** (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, aureomycin, chloramphenicol, or bacitracin or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.



(c) Whenever in the judgment of the Administrator, the requirements of this section and of section 502 (1) with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Administrator shall promulgate regulations exempting such drug or class of drugs from such requirements.

(d) The Administrator shall promulgate regulations exempting from any requirement of this section and of section 502(1), (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

(e) No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505. Compliance of any drug subject to section 502(1) or 507 with sections 501 (b) and 502 (g) shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under section 507.

(f) Any interested person may file with the Administrator a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 701 (f) and (g).

## CHAPTER VI—COSMETICS

### Adulterated Cosmetics

**Sec. 601.** A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.



(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

### Misbranded Cosmetics

**Sec. 602.** A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

### Regulations Making Exemptions

**Sec. 603.** The Administrator shall promulgate regulations exempting from any labeling requirements of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

### Certification of Coal-Tar Colors for Cosmetics

**Sec. 604.** The Administrator shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

## CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

### Regulations and Hearings

**Sec. 701.** (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Administrator.

(b) The Secretary of the Treasury and the Federal Security Administrator shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Federal Security Administrator shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Administrator or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403(j),



404(a), 406(a) and (b), 501(b), 502(d), 502(h), 504, and 604. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404(a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necessitating an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Administrator, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Administrator based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Administrator refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Administrator to take action, with respect to such regulation, in accordance with law. The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Administrator shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Administrator or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Administrator to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).



### Examinations and Investigations

**Sec. 702.** (a) The Administrator is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Agency or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Administrator as an officer of the Agency. In the case of food packed in a Territory the Administrator shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Administrator shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Administrator is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Federal Security Agency duly authorized by the Administrator to make such inspection.

### Sea-Food Inspection

**Sec. 702A.<sup>1</sup>** The Federal Security Administrator, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Federal Security Administrator for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Administrator is hereby authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than \$1,000 nor more than \$5,000 or both such imprisonment and fine.

### Records of Interstate Shipment

**Sec. 703.** For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit

<sup>1</sup> Sec. 902 (a) provides that the amendment to the Food and Drugs Act, Section 10A, shall remain in force and effect and be applicable to the provisions of this Act. The Labor-Federal Security Appropriation

Act of July 12, 1943 (ch. 221, title II, § 1, 57 Stat. 500) renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act. Title 21 U. S. C., 1946 ed. codifies this section as 372 a.



such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

### Factory Inspection

**Sec. 704.** For purposes of enforcement of this Act, officers or employees duly designated by the Administrator, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

### Publicity

**Sec. 705.** (a) The Administrator shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Administrator may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Administrator, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Administrator from collecting, reporting, and illustrating the results of the investigations of the Agency.

### Cost of Certification of Coal-Tar Colors

**Sec. 706.** The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

## CHAPTER VIII—IMPORTS AND EXPORTS

**Sec. 801.** (a) The Secretary of the Treasury shall deliver to the Federal Security Administrator, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Federal Security Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. This



paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U. S. C., 1934 edition, title 21, sec. 173).

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Administrator that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Federal Security Agency designated by the Administrator, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorization under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

## CHAPTER IX—MISCELLANEOUS

### Separability Clause

Sec. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

### Effective Date and Repeals

Sec. 902. (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary [of Agriculture] is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary [of



Agriculture] shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further*, That sections 502(j), 505, and 601(a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a [49 Stat. 871, ch. 739]), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71-91; 34 Stat. 1260 et seq.)

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Virus, Serum, and Toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, ch. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61-63); or the Import Milk Act of February 15, 1927 (U. S. C., 1934 ed., title 21, ch. 4, secs. 141-149).

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

Approved June 25, 1938. Amended June 23, 1939, December 22, 1941, July 6, 1945, March 10, 1947, June 24, 1948, July 13, 1949, and October 18, 1949.

---



# THE POSTPONEMENT ACT

(Public—No. 151—Seventy-Sixth Congress, Chapter 242, First Session, H. R. 5762; 53 Stat. 853 and 854.)

(PUBLIC—NO. 151—76th CONGRESS)

## AN ACT

To provide for temporary postponement of the operations of certain provisions of the Federal Food, Drug, and Cosmetic Act.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

That (a) the effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c); 403(e)(1); 403(g), (h), (i), (j), and (k); 501(a)(4); 502(b), (d), (e), (f), (g), and (h); 601(e); and 602(b).

(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940, the effective date of the provisions of sections 403(e)(1); 403(g), (h), (i), (j), and (k); 502(b), (d), (e), (f), (g), and (h), and 602(b) of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: *Provided*, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

**Sec. 2.** (a) The provisions of section 8, paragraph fifth, under the heading "In the case of food:", of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 and of such regulations, shall remain in force until January 1, 1940.

(b) The provisions of such Act of June 30, 1906, as amended, to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act, shall remain in force until January 1, 1940.

(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to any substance named in section 8, paragraph second, under the heading "In the case of drugs:", of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to drugs to which section 505 of such Act applies.

**Sec. 3.** Section 502(d) of the Federal Food, Drug, and Cosmetic Act is hereby amended by striking out the words "name, quantity, and percentage" where they appear therein and substituting in lieu thereof "name, and quantity or proportion".

Approved June 23, 1939.



# THE BUTTER ACT<sup>1</sup>

(Public—No. 519—Sixty-Seventh Congress, Fourth Session, Chapter 268, H. R. 12053; 42 Stat. 1500.)

## AN ACT

To define butter and to provide a standard therefor.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

That for the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768), "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

Approved March 4, 1923.

---

---

<sup>1</sup> The Butter Act was made applicable to the Federal Food, Drug, and Cosmetic Act

of 1938 by Section 902(a) of that Act.  
—Author.



# THE WRAPPED MEATS ACT<sup>1</sup>

(Public — No. 22 — Sixty-Sixth Congress, First Session, Chapter 26, H. R. 7413; 41 Stat. 234, 271.)

## AN ACT

Making appropriations for the Department of Agriculture for the fiscal year ending June 30, 1920.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

\* \* \*

That the word "package" where it occurs the second and last time in the act entitled "An act to amend section 8 of an act entitled 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,'" approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

\* \* \*

Approved July 24, 1919.

---

<sup>1</sup> The Wrapped Meats Act was made applicable to the Federal Food, Drug, and

Cosmetic Act of 1938 by Section 902 (a) of that Act.—Author.



# THE SKIM MILK ACT

(Public—No. 244—Seventy-Eighth Congress, Second Session, Chapter 77, H. R. 149; 58 Stat. 108.)

## AN ACT

To fix a reasonable definition and standard of identity of certain dry milk solids.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

That for the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), nonfat dry milk solids or defatted milk solids is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows.

Approved March 2, 1944.

---



FORMS

FORM OF CLAIM

IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_  
\_\_\_\_\_ DIVISION

United States of America  
v.  
720 Cartons, More or Less, each con-  
taining 12 boxes of an article labeled  
"\_\_\_\_\_"

} No. \_\_\_\_\_

Now appears before this Honorable Court \_\_\_\_\_ Company, a corpora-  
tion duly organized and existing under the laws of the State of \_\_\_\_\_,  
with its principal place of business in the City of \_\_\_\_\_, State of  
\_\_\_\_\_, intervening in this proceeding for the interest of itself as  
owner of the article above described, and makes claim to the said article as the  
same is attached by the United States Marshal for this district under process of  
this Court at the instance of the United States of America, libelant;

And said claimant avers that it is the true and bona fide sole owner of the  
said article and that no other person is the owner thereof; wherefore it prays to  
defend accordingly.

\_\_\_\_\_  
By: \_\_\_\_\_  
\_\_\_\_\_

STATE OF \_\_\_\_\_ }  
COUNTY OF \_\_\_\_\_ } ss. :

\_\_\_\_\_, being duly sworn, deposes and  
says that he is the \_\_\_\_\_ of \_\_\_\_\_ Company, the cor-  
poration which is described in and which executed the foregoing Claim; that he  
has authority to act on behalf of the corporation in this matter and that he signed  
said Claim pursuant to said authority; that he has read said Claim and knows the  
contents thereof, and that the same is true to the best of his knowledge, informa-  
tion, and belief; and that he knows that the seal affixed to said Claim is the seal  
of said corporation and was duly affixed as such.

Sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_,  
19\_\_\_\_.

\_\_\_\_\_  
Notary Public



# FORM OF CONSENT DECREE OF CONDEMNATION PERMITTING SALVAGING OF PRODUCT

IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_  
\_\_\_\_\_ DIVISION

United States of America

v.

720 Cartons, More or Less, each con-  
taining 12 boxes of an article labeled  
"\_\_\_\_\_"

No. \_\_\_\_\_, \_\_\_\_\_

On \_\_\_\_\_, 19\_\_\_\_, a libel of information against the above described article was filed in this Court on behalf of the United States of America by the United States Attorney and the Assistant United States Attorney for this district. The libel alleges that the article proceeded against is a food which was shipped in interstate commerce and is adulterated in violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). Pursuant to Monition issued by this Court, the United States Marshal for this district seized said article on \_\_\_\_\_, 19\_\_\_\_. Thereafter, \_\_\_\_\_ Company of \_\_\_\_\_, \_\_\_\_\_, intervened and filed claim to said article. Claimant consents that a Decree, as prayed for in the libel, be entered condemning the article under seizure.

The Court being fully advised in the premises, it is on motion of the parties hereto—

ORDERED, ADJUDGED AND DECREED that the said article under seizure is adulterated in violation of 21 U.S.C. 342(a)(3), and is therefore hereby condemned pursuant to 21 U.S.C. 334(a); and it is further

ORDERED, ADJUDGED AND DECREED, pursuant to 21 U.S.C. 334(e), that the United States of America shall recover from said claimant court costs and fees, and storage and other proper expenses, as taxed herein, to wit, the sum of \$\_\_\_\_\_; and

Claimant having petitioned this Court that the condemned article be delivered to it pursuant to 21 U.S.C. 334(d), it is further

ORDERED, ADJUDGED AND DECREED that the United States Marshal for this district shall release said article from his custody to the custody of claimant for the purpose of converting said article into stock feed if claimant, within 20 days from the date of this decree, (a) pays in full the aforementioned court costs and fees, and storage and other proper expenses of the proceeding herein, and (b) executes and files with the clerk of this Court a good and sufficient penal bond with surety in the sum of \_\_\_\_\_ Dollars (\$\_\_\_\_\_), approved by this Court, payable to the United States of America, and conditioned on the claimant's abiding by and performing all the terms and conditions of this Decree and of such further Orders and Decrees as may be entered in this proceeding; and it is further

ORDERED, ADJUDGED AND DECREED that:

1. After the filing of the bond in this Court, the claimant shall, at its own expense, cause the article to be shipped to its plant at \_\_\_\_\_. When the article arrives at the \_\_\_\_\_ plant, claimant shall give written notice to the \_\_\_\_\_ District, Food and Drug Administration, Federal Security Agency, \_\_\_\_\_, that the article has arrived and that claimant is prepared to convert it into stock feed under the supervision of a duly authorized representative of the Federal Security Administrator.



2. The claimant shall at all times, until the article has been released by a duly authorized representative of the Federal Security Administrator, retain intact the entire lot of goods comprising the article for examination or inspection by said representative, and shall maintain the records or other proof necessary to establish the identity of said lot to the satisfaction of said representative.

3. The claimant shall not commence conversion operations until it has received authorization to do so from a duly authorized representative of the Federal Security Administrator.

4. The claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of any part of said article or of the article into which it is converted until a duly authorized representative of the Federal Security Administrator shall have had free access thereto in order to take any samples or make any tests or examinations that are deemed necessary, and shall in writing have released such article for shipment, sale, or other disposition.

5. Within 30 days from the date of the filing of the bond in this Court, claimant shall complete the process of converting said article into stock feed at its \_\_\_\_\_, \_\_\_\_\_, plant under the supervision of a duly authorized representative of the Federal Security Administrator.

6. The claimant shall abide by the decisions of said duly authorized representative of the Federal Security Administrator, which decisions shall be final. If claimant breaches any conditions stated in this Decree, or in any subsequent Decree or Order of this Court in this proceeding, claimant shall return the article immediately to the United States Marshal for this district at claimant's expense, or shall otherwise dispose of it pursuant to an Order of this Court.

7. The claimant shall not sell or dispose of said article or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State or Territory (as defined in said Act) in which it is sold or disposed of.

8. The claimant shall compensate the United States of America for cost of supervision at the rate of \$\_\_\_\_\_ per day per representative for each day actually employed in the supervision of the conversion process, as salary or wage; where laboratory work is necessary, at the rate of \$\_\_\_\_\_ per day per person for such laboratory work; where subsistence expenses are incurred, at the rate of \$\_\_\_\_\_ per day per person for such subsistence expenses. Claimant shall also compensate the United States of America for necessary traveling expenses and for any other necessary expenses which may be incurred in connection with the supervisory responsibilities of said Federal Security Administrator.

9. If requested by a duly authorized representative of the Federal Security Administrator, claimant shall furnish to said representative duplicate copies of invoices of sale of the released article, or shall furnish such other evidence of disposition as said representative may request.

The United States Attorney for this district, on being advised by a duly authorized representative of the Federal Security Administrator that the conditions of this Decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the bond given in this proceeding shall be canceled and discharged; and it is further

ORDERED, ADJUDGED AND DECREED that if the claimant does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this district shall retain custody of said article pending the issuance of an order by this Court regarding its disposition; and it is further

ORDERED, ADJUDGED AND DECREED that this Court expressly retains jurisdiction to issue such further DECREES and Orders as may be necessary to the proper disposition of this proceeding, and that should the claimant fail to abide by and perform all the terms and conditions of this Decree, or of such further Order or Decree as may be entered in this proceeding, or of said bond, then said bond shall on motion of the United States of America in this proceeding be forfeited and judgment entered thereon.



Dated at \_\_\_\_\_, \_\_\_\_\_, this \_\_\_\_\_  
of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States District Judge

We hereby consent to the entry of the foregoing Decree.

\_\_\_\_\_  
United States Attorney  
By

\_\_\_\_\_  
Assistant United States Attorney

\_\_\_\_\_  
Proctor for Claimant



# FORM OF BOND FURNISHED PURSUANT TO DECREE PERMITTING SALVAGING

IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_

\_\_\_\_\_ DIVISION

\_\_\_\_\_ Term, A.D., 19\_\_\_\_

United States of America

v.

No. \_\_\_\_\_, \_\_\_\_\_

BOND

KNOW ALL MEN BY THESE PRESENTS: That \_\_\_\_\_

\_\_\_\_\_, as Principal, and \_\_\_\_\_, a corporation duly organized under the laws of the State of \_\_\_\_\_, and having a place of business at \_\_\_\_\_, as Surety, are held and firmly bound unto the United States of America in the sum of \_\_\_\_\_ (\$\_\_\_\_\_) Dollars, for the payment of which to the United States of America they bind themselves, their representatives, successors, and assigns, jointly and severally, firmly by these presents.

WHEREAS, on \_\_\_\_\_, 19\_\_\_\_, a decree was entered in the above-described proceeding, a copy of which Decree is hereto annexed, marked Exhibit A, and made a part hereof;

NOW, THEREFORE, the condition of this obligation is such that if the said Principal shall abide by and perform all the terms and conditions of said Decree and of such further Orders and Decrees as may be entered by the above-designated Court in this proceeding, then this obligation shall become null and void; otherwise it shall remain in full force and effect.

And the said Principal and Surety covenant and agree that, by entering into and furnishing this Bond, they submit themselves, and each of them, to the jurisdiction of the above-designated Court and irrevocably appoint the Clerk of said Court as their agent upon whom any papers affecting their liability on said Bond may be served, that their liability on and under said Bond may be enforced on motion made in and to said Court without the necessity of an independent action, and that said motion and notice thereof may be served on the said Clerk of said Court.

Signed with our hands and seals this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
By \_\_\_\_\_ } Principal

\_\_\_\_\_  
By \_\_\_\_\_ } Surety

Attest:

\_\_\_\_\_  
Secretary

Bond approved

\_\_\_\_\_, 19\_\_\_\_.



# FORM OF PETITION FOR EXONERATION OF, AND FORM OF ORDER EXONERATING, BOND

IN THE DISTRICT COURT OF THE UNITED STATES

FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_

\_\_\_\_\_  
DIVISION

United States of America,  
Libelant,

v.

No. \_\_\_\_\_, \_\_\_\_\_

31 CASES, ..... }

Comes now \_\_\_\_\_, a corporation, claimant herein, and petitions the Court and alleges as follows:

That claimant has relabeled the article of food described in the caption hereof which was delivered to it for relabeling pursuant to the order entered herein March 22, 1945, in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act and under the supervision of a representative duly designated for that purpose by the Federal Security Administrator, and has brought said article into full compliance with said Act and has paid all expenses of supervision, court costs and fees, storage and other proper expenses herein in connection with said relabeling as required by said order.

WHEREFORE, claimant prays that the bond for release of said article of food, dated March 6, 1945, and filed herein, be exonerated and said article of food be finally released to it.

\_\_\_\_\_  
By \_\_\_\_\_

Consented to:

\_\_\_\_\_  
United States Attorney  
Proctor for Libelant

By \_\_\_\_\_  
Assistant United States Attorney

STATE OF \_\_\_\_\_ }  
COUNTY OF \_\_\_\_\_ } ss.:

\_\_\_\_\_, being first duly sworn, deposes and says:

That he is the \_\_\_\_\_ of \_\_\_\_\_, the petitioner above named, and is authorized to make this verification for and on behalf of said corporation; that he has read the foregoing Petition for Exoneration of Bond, knows the contents thereof, and believes it to be true.

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
Notary Public in and for the State of \_\_\_\_\_, County of \_\_\_\_\_



IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_  
\_\_\_\_\_ DIVISION

United States of America,	}	No. _____, _____
Libelant,		
v.		
31 CASES, .....	}	

This cause having regularly come on for hearing this day upon the petition of \_\_\_\_\_, a corporation, claimant herein, for exoneration of the bond heretofore filed by it herein and final release to it of the article of food described in the caption hereof, and it appearing to the Court that said claimant has relabeled said article of food in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act and has brought said article of food into full compliance with said Act and has paid all expenses of supervision, court costs and fees, storage and other proper expenses herein and in connection with said relabeling as required by the order of this Court entered herein March 22, 1945, and it further appearing that the libelant interposes no objection to the entry of this order, Now, Therefore, it is

ORDERED that said article of food be and the same is hereby finally released to said claimant and the bond for release thereof, dated March 6, 1945, and filed herein by said claimant, with the \_\_\_\_\_ Company, a corporation, as surety, be and the same is hereby canceled and exonerated.

Dated at \_\_\_\_\_, \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States District Judge



FORM OF ANSWER ADMITTING ALLEGATIONS OF LIBEL  
AND PETITIONING FOR RELEASE OF PRODUCT  
FOR SALVAGING

IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE DISTRICT OF \_\_\_\_\_

United States of America  
v.  
26 bags, more or less, of an article of  
food labeled in part: "\_\_\_\_\_  
\_\_\_\_\_".

No. \_\_\_\_\_, \_\_\_\_\_

TO THE HONORABLE, THE JUDGES OF SAID COURT:

The Petition and Answer of \_\_\_\_\_, claimant  
in this libel proceeding, respectfully represents:

1. That claimant \_\_\_\_\_ is the owner of the pro-  
perty libeled and has made claim to the said property.

2. That claimant admits the allegations contained in the libel filed herein,  
but alleges that the adulteration, as alleged in the libel, was unintentional and due  
to inadvertence.

3. That claimant assents to the entry of a decree condemning the afore-  
said libeled property and forfeiting all rights, title, and interest of any and all per-  
sons therein to the United States of America, but prays that said property may be  
released to it for denaturing for use as animal feed under the supervision of a duly  
authorized representative of the Federal Security Administrator.

4. That claimant is willing to pay the costs of this proceeding and to furnish  
a good and sufficient bond pursuant to the provisions of Section 304(d) of the  
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)).

WHEREFORE, claimant prays this Honorable Court to enter an order condemn-  
ing the aforesaid property and forfeiting all rights, title, and interest of any and all  
persons therein to the United States of America, and authorizing the release of  
said property to claimant for the purpose aforesaid in accordance with the pro-  
visions of Section 304(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
334(d)).

\_\_\_\_\_  
Claimant

By \_\_\_\_\_

STATE OF \_\_\_\_\_ }  
COUNTY OF \_\_\_\_\_ } ss.:

I hereby certify that before me, a Notary Public in and for the County afore-  
said, in the State aforesaid, personally appeared \_\_\_\_\_, of \_\_\_\_\_,  
who says that he is \_\_\_\_\_ of \_\_\_\_\_, claimant in the  
above-captioned libel proceeding, and that the matters and facts alleged in the  
aforegoing petition and answer are true to the best of his knowledge, information,  
and belief.

\_\_\_\_\_  
Notary Public

I consent to the relief prayed:

\_\_\_\_\_  
United States Attorney  
Proctor for Libelant

By \_\_\_\_\_  
Assistant United States Attorney



# FORM OF ORDER ACCELERATING RETURN OF MONITION, ETC.

UNITED STATES DISTRICT COURT

DISTRICT OF \_\_\_\_\_

United States of America  
v.  
1008 Boxes, More or Less, of "\_\_\_\_\_  
\_\_\_\_\_."

No. \_\_\_\_\_, \_\_\_\_\_

It appearing that a monition was issued on November 23, 1945, in the above matter to the United States Marshal for the District of \_\_\_\_\_, returnable December 24, 1945, under which the food referred to in the libel of information filed herein, consisting of 1008 boxes, more or less, of apples, was attached by said Marshal at \_\_\_\_\_, in this District, on November 27, 1945; and it further appearing that \_\_\_\_\_, Incorporated, has duly filed its claim and deposited \$\_\_\_\_\_ in lieu of a stipulation for claimant's costs with the Clerk of this Court, and that acceleration of said return day is necessary in order that said food which is perishable may be immediately processed, if possible, under supervision of the Food and Drug Administration of the Federal Security Agency on entry of an appropriate decree herein so that said food or part thereof may be made fit for human consumption, and the United States Attorney consenting hereto,

It Is, on this 7th day of December, 1945, on motion of \_\_\_\_\_, proctors for said claimant,

ORDERED that the return day of the aforesaid process and monition issued November 23, 1945, be and the same is hereby accelerated to the day of the date of this order, and it is

FURTHER ORDERED that a bond in the amount of \$\_\_\_\_\_ or cash in lieu thereof shall be deposited by claimant with the Clerk of this Court for the use of the libelant under the Decree about to be entered herein and shall also be for the use of, and to indemnify and hold harmless, the United States Marshal for the District of \_\_\_\_\_ from all claims to ownership of said libeled merchandise that may be made against him by any other persons.

\_\_\_\_\_  
United States District Judge

We hereby consent to the making and entry of the foregoing order:

\_\_\_\_\_  
United States Attorney  
Proctor for Libelant

By \_\_\_\_\_  
Assistant United States Attorney

\_\_\_\_\_  
Proctor for Claimant



FORM OF ANSWER  
IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE DISTRICT OF\_\_\_\_\_

United States of America  
v.  
194 Cases, More or Less, each contain-  
ing 48 cans of an article labeled in part  
"\_\_\_\_\_."

No. \_\_\_\_\_, \_\_\_\_\_

The answer of \_\_\_\_\_ and \_\_\_\_\_, Co-partners, trading as  
\_\_\_\_\_ Company, claimants in the above entitled case, respectfully  
represents:

1. That they admit the allegations contained in paragraphs numbered 1 and 2 of the libel herein filed.
2. That they deny each and every allegation contained in paragraphs numbered 3 and 5 of the libel herein filed.
3. That they deny that they have any knowledge or information sufficient to form a belief as to the allegations contained in paragraph numbered 4 of the libel herein filed.

And for further answer they say that they are the packers, shippers, and owners of the product herein libelled, that said product contains fresh cod, and that said product is not adulterated within the meaning or in violation of 21 U.S.C. 342(a)(3) or otherwise.

WHEREFORE having fully answered, they respectfully pray:

1. That an order be entered allowing them to obtain representative samples of the libelled product.
2. That the libel herein filed be dismissed.
3. And for such other and further relief as to the Court may seem just and proper.

\_\_\_\_\_  
Company,

By: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

STATE OF \_\_\_\_\_  
COUNTY OF \_\_\_\_\_

ss.:

\_\_\_\_\_ and \_\_\_\_\_, being first duly sworn, according to law, depose and say that they have read the foregoing annexed answer by them subscribed and that they know the contents thereof, and that the matters and things therein stated they verily believe are true.

\_\_\_\_\_  
\_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
Notary Public  
My commission expires \_\_\_\_\_.



# FORM OF ORDER PERMITTING WITHDRAWAL OF CLAIM AND ANSWER

UNITED STATES DISTRICT COURT

DISTRICT OF \_\_\_\_\_

United States of America

v.

216 Cartons, more or less, each containing 18 boxes of an article labeled in part: "\_\_\_\_\_."

No. \_\_\_\_\_, \_\_\_\_\_

This action having been commenced by the filing of a libel on December 28, 1945, in the District Court of the United States for the District of Massachusetts, and \_\_\_\_\_, by \_\_\_\_\_, a partner, having duly filed a claim of ownership and an answer having been timely interposed on March 8, 1946, and an order having been entered on March 14, 1946, in the District Court of the United States for the District of Massachusetts, removing this action for trial to the District Court of the United States for the \_\_\_\_\_ District of \_\_\_\_\_,

Now, on motion of the claimant herein, and upon the attached consent of the proctor for the libellant, and upon all the proceedings had herein, it is hereby

ORDERED, ADJUDGED, AND DECREED that the claim and answer previously filed herein by claimant be and the same hereby are withdrawn; and it is further

ORDERED, ADJUDGED, AND DECREED that the goods, wares, and merchandise above mentioned are misbranded and the same accordingly are condemned and forfeited to the United States of America; and it is further

ORDERED, ADJUDGED, AND DECREED that the Clerk of this Court issue a writ of destruction to the United States Marshal for the District of Massachusetts, returnable according to law; and it is further

ORDERED, ADJUDGED, AND DECREED that the fees and expenses of the United States Marshal for the District of Massachusetts in the sum of \$\_\_\_\_\_ shall be paid by the claimant to the said United States Marshal; and it is further

ORDERED, ADJUDGED, AND DECREED that the costs of this proceeding in the sum of \$\_\_\_\_\_ shall be paid by the claimant to the Clerk of the United States

District Court for the \_\_\_\_\_ District of \_\_\_\_\_.

Dated: \_\_\_\_\_, \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States District Judge



UNITED STATES DISTRICT COURT

DISTRICT OF

United States of America

v.

216 Cartons, more or less, each contain-  
ing 18 boxes of an article labeled in  
part: "\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_."

\_\_\_\_\_  
Company, claimant herein, does hereby  
admit the truth of the allegations of the libel filed herein and does hereby consent  
to the entry of the foregoing decree.

Dated: \_\_\_\_\_, \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
Company  
By \_\_\_\_\_

STATE OF \_\_\_\_\_

COUNTY OF \_\_\_\_\_

ss.:

On this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_, before me personally appeared  
\_\_\_\_\_, to me known and known to me to be the indi-  
vidual described in and who executed the foregoing instrument.

\_\_\_\_\_  
Notary Public  
My Commission Expires \_\_\_\_\_, 19\_\_\_\_.

The undersigned proctor for libelant hereby consents to the entry of the fore-  
going decree.

Dated: \_\_\_\_\_, \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States Attorney  
Proctor for Libelant  
By \_\_\_\_\_  
Assistant United States Attorney



# FORM OF MOTION TO VACATE DECREE ENTERED ON DEFAULT AND ORDER OPENING DEFAULT

UNITED STATES DISTRICT COURT  
DISTRICT OF \_\_\_\_\_

United States of America

v.

2 cans, more or less, of an article  
labeled in part:

"\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_" ; etc.

No. \_\_\_\_\_, \_\_\_\_\_

Now COMES \_\_\_\_\_, the claimant herein, and respectfully petitions this Court to vacate and set aside the decree of condemnation entered herein on the 21st day of October, 1946; that this cause be re-opened; that the claimant's claim of ownership be reinstated; and for such other and further relief as may be deemed proper.

In support of the foregoing there is herewith submitted and annexed the affidavit of \_\_\_\_\_, verified \_\_\_\_\_.

By: \_\_\_\_\_

Proctor for Claimant



UNITED STATES DISTRICT COURT  
DISTRICT OF \_\_\_\_\_

United States of America  
v.  
2 cans, more or less, of an article  
labeled in part:  
"\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_" ; etc.

No. \_\_\_\_\_, \_\_\_\_\_

COUNTY OF \_\_\_\_\_  
STATE OF \_\_\_\_\_ } ss.:

\_\_\_\_\_, being duly sworn, deposes and says as follows:

I am the Secretary-Treasurer of \_\_\_\_\_, the claimant named in the foregoing petition.

Claimant is a corporation organized and existing under the laws of the State of \_\_\_\_\_, located at \_\_\_\_\_. It is the owner of the seized merchandise, which is the subject of this libel proceeding. The said seized merchandise comprises \_\_\_\_\_, the total value thereof being approximately \$3700.00.

The libel herein was filed on August 17, 1945. On September 15, 1945, the claimant filed a Stipulation of Costs and its Claim of Ownership with respect to the seized merchandise. On October 15, 1946, the claimant filed a withdrawal of the said claim of ownership. Thereafter, and on October 21, 1946, a decree of condemnation was signed and entered directing the destruction of the seized merchandise.

Claimant believes that most of the dyes of the seized merchandise are made from properly certified dyes, and that at least eleven cans of the seized merchandise, having a value of approximately \$2500.00, contain certified colors. Claimant is desirous of avoiding the destruction and loss of such of the seized merchandise as it believes would be certified, having the minimum value of \$2500.00. The consent to the decree of condemnation of October 2, 1946, was inadvertently given without realization of the foregoing.

Claimant therefore respectfully prays that this Court vacate and set aside the decree of condemnation entered October 21, 1946; that this proceeding be reopened; and that the claimant's claim of ownership be reinstated; all for the purpose of obtaining certification of such of the seized material as may be certified.

Sworn to before me this 14th day of  
September, 1948.

\_\_\_\_\_  
Notary Public

My Commission Expires: \_\_\_\_\_



UNITED STATES DISTRICT COURT  
DISTRICT OF \_\_\_\_\_

United States of America

v.

2 cans, more or less, of an article  
labeled in part:

"\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_"; etc.

No. \_\_\_\_\_, \_\_\_\_\_

The claimant, \_\_\_\_\_, having moved this court by petition dated September 14, 1948, for an order to set aside the decree of condemnation and to reopen this cause, it is hereby ORDERED as follows upon consent of the parties:

1. That the decree of condemnation entered herein on the 21st day of October, 1946, be and the same hereby is vacated and set aside, and that this cause be reopened;

2. That claimant's claim of ownership be reinstated.

\_\_\_\_\_  
United States District Judge

The entry of the above decree is here-  
with consented to:

\_\_\_\_\_  
U.S. Attorney  
Proctor for Libelant

By \_\_\_\_\_  
Assistant U.S. Attorney

\_\_\_\_\_  
Proctor for Claimant



FORM OF  
STIPULATION AND ORDER CONSOLIDATING AND  
REMOVING SEIZURE ACTION

IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE DISTRICT OF \_\_\_\_\_

United States of America,  
Libelant,

v.

36 Cases, More or Less, of

"\_\_\_\_\_."

No. \_\_\_\_\_, \_\_\_\_\_

IT IS HEREBY STIPULATED AND AGREED by \_\_\_\_\_,  
United States Attorney, proctor for the libelant, and \_\_\_\_\_,  
proctor for the claimant, that pursuant to the authority contained in 21 U.S.C.  
334 (b), the above-entitled action shall be removed to the United States District  
Court for the \_\_\_\_\_ District of \_\_\_\_\_  
and there consolidated for trial with the action entitled "United States of America  
v. 45 Cases, More or Less, of \_\_\_\_\_," involving the same  
claimant and issue of adulteration as are involved in the above-entitled action;  
and it is further

STIPULATED AND AGREED that an order be made directing the clerk of the  
United States District Court for the District of \_\_\_\_\_  
to transmit the records in the above-entitled action to the clerk of the United  
States District Court for the \_\_\_\_\_ District of \_\_\_\_\_

Dated: \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States Attorney  
Proctor for Libelant

By \_\_\_\_\_  
Assistant United States Attorney

\_\_\_\_\_  
Proctor for Claimant



At a Stated Term of the United  
States District Court for the District  
of \_\_\_\_\_, in the United  
States Courthouse, \_\_\_\_\_,  
\_\_\_\_\_, on the \_\_\_\_\_  
day of \_\_\_\_\_, 19\_\_\_\_

Present:

Hon. \_\_\_\_\_,  
Justice

United States of America,  
Libelant

v.

36 Cases, More or Less, of

"\_\_\_\_\_."

No. \_\_\_\_\_

Upon the annexed stipulation of consent dated \_\_\_\_\_, 19\_\_\_\_,  
it is hereby

ORDERED, pursuant to Section 304 (b) of the Federal Food, Drug, and Cos-  
metic Act (21 U.S.C. 334 (b)), that the above-entitled action be removed to the  
United States District Court for the \_\_\_\_\_ District of  
\_\_\_\_\_, and there consolidated for trial with the action entitled  
"United States of America v. 45 Cases, More or Less, of \_\_\_\_\_,"  
involving the same claimant and the same issue of adulteration as are involved in  
the above-entitled action; and it is further

ORDERED, that the clerk of the United States District Court for the District  
of \_\_\_\_\_ promptly transmit a certified copy of this order and  
the records in the above-entitled action to the clerk of the United States District  
Court for the \_\_\_\_\_ District of \_\_\_\_\_,  
pursuant to Section 304 (f) (1) of the Federal Food, Drug, and Cosmetic Act (21  
U.S.C. 334 (f) (1)).

ENTER

\_\_\_\_\_  
United States District Judge



FORM OF INTERROGATORIES

IN THE UNITED STATES DISTRICT COURT  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_

United States of America, Plaintiff, v. _____, INC., Defendant.	No. _____, _____
---	------------------

Now comes the defendant in this action, pursuant to rule 33 of the Federal Rules of Civil Procedure, and files the following interrogatories to be answered separately and fully in writing under oath by the plaintiff through its proper officer, agent or employee.

Give the answers to each of the following questions with respect to each of the following drugs mentioned in paragraphs "4" and "6" of the complaint;  
"\_\_\_\_\_."

- 1. State when said drug was introduced into interstate commerce by the defendant in violation of the Federal Food, Drug, and Cosmetic Act.
- 2. Where did the plaintiff obtain samples of said drug, on what date, and from whom?
- 3. Was the sample obtained by the plaintiff contained in a vial or ampule?
- 4. What was the size of the vial or ampule in which the drug was contained?
- 5. What was the lot number or numbers on the label on the vial or ampule in which said drug was contained? If the plaintiff obtained more than one sample state the number of samples it obtained of said drug, and if they were in different vials or ampules state the size of each of the vials and ampules and the respective lot numbers shown on the labels.
- 6. State in detail what was done with each sample of said drug prior to its examination.
- 7. State when and where such examination was made and by whom made.
- 8. State in detail the qualifications of the person making such examination.
- 9. State in detail the method employed by such person in making the examination.
- 10. Describe in detail any and all devices and techniques used in the examination of said drug during the examination.
- 11. How were the ampules or vials of each sample of said drug treated or handled by plaintiff before examination?
- 12. Set forth in detail each of the steps followed in making each of said examinations.
- 13. What has been the care and treatment of each of said samples of said drugs which were examined since the date of each of said examinations?

The answers to these interrogatories shall be signed by the person making them, and a copy of the answers shall be served upon counsel for the defendant within fifteen (15) days after the service of these interrogatories.

\_\_\_\_\_  
Attorneys for Defendant



## FORM OF CONSENT DECREE OF INJUNCTION AND RELATED PAPERS

UNITED STATES DISTRICT COURT

DISTRICT OF \_\_\_\_\_

United States of America,  
Plaintiff,

v.

Defendant.

No. \_\_\_\_\_, \_\_\_\_\_

Upon reading and filing the annexed affidavit of \_\_\_\_\_, Assistant United States Attorney in and for the \_\_\_\_\_ District of \_\_\_\_\_, and upon the consent of the defendant herein, and upon all the pleadings and proceedings herein heretofore had and the papers herein now on file in the office of the Clerk of this Court, and it appearing that the plaintiff is entitled to the relief demanded in the complaint;

Now, on motion of \_\_\_\_\_, United States Attorney in and for the \_\_\_\_\_ District of \_\_\_\_\_, it is hereby

ORDERED, ADJUDGED, AND DECREED as follows:

1. That this Court has jurisdiction of the subject matter hereof and of all the persons herein.

2. That \_\_\_\_\_, his agents, servants, employees, and attorneys, and all persons in active concert or participation with them, be perpetually enjoined from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce a food, to wit, cherry juice, which is in violation of the Federal Food, Drug, and Cosmetic Act as set forth and described in the body of the bill of complaint herein, a copy of which complaint is hereto annexed and made a part of this judgment, or otherwise in violation of Section 402(a)(3) and (4) of said Act.

3. That jurisdiction of this Court is retained for the purpose of enforcing this decree and for the purpose of furnishing such additional relief as may hereafter appear necessary or appropriate.

4. That the defendant shall pay all costs involved in this proceeding.

Dated: \_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
United States District Judge



## UNITED STATES DISTRICT COURT

DISTRICT OF \_\_\_\_\_

United States of America,  
Plaintiff,

v.

Defendant.

No. \_\_\_\_\_, \_\_\_\_\_

STATE OF \_\_\_\_\_

COUNTY OF \_\_\_\_\_

ss.:

\_\_\_\_\_, being duly sworn,  
deposes and says that he is an Assistant United States Attorney in and for the  
\_\_\_\_\_ District of \_\_\_\_\_ and, as such, has  
had charge of the above-entitled proceeding since the inception thereof, under the  
direction of \_\_\_\_\_, United States Attorney in  
and for the \_\_\_\_\_ District of \_\_\_\_\_.

That heretofore and on the 4th day of October, 1948, the complaint herein  
was filed in the office of the Clerk of this Court, said complaint praying for a  
judgment decreeing that the above-named defendant, his agents, servants, em-  
ployees, and attorneys, and all persons in active concert or participation with  
them, be perpetually enjoined from directly or indirectly introducing or causing  
to be introduced, or delivering or causing to be delivered for introduction, into  
interstate commerce a food, to wit, cherry juice, which is adulterated within the  
meaning of the Act, 21 U.S.C. 342 (a) (3) and (4).

That on or about the said 4th day of October, 1948, a summons was issued  
by the Clerk of this Court and a copy thereof, together with a copy of the com-  
plaint, was served on the defendant, as more fully appears by the return of  
\_\_\_\_\_, Deputy United States Marshal in  
and for the \_\_\_\_\_ District of \_\_\_\_\_, which  
said return was filed in the office of the Clerk of this Court on October 6, 1948.

That the defendant has consented to the entry of a decree of permanent  
injunction.

WHEREFORE, your deponent respectfully prays for a judgment decreeing a  
permanent injunction against the defendant for the relief demanded in said  
complaint.

Sworn to before me this \_\_\_\_\_

day of \_\_\_\_\_, 19\_\_\_\_.

Commissioner of Deeds in and for the City  
of \_\_\_\_\_,

County, \_\_\_\_\_.



IN THE DISTRICT COURT OF THE UNITED STATES  
FOR THE \_\_\_\_\_ DISTRICT OF \_\_\_\_\_

United States of America,	}	No. _____, _____
Plaintiff,		
v. _____,		
Defendant.		

The above-named defendant hereby consents and stipulates that a permanent injunction may be issued and entered in the above-entitled action perpetually enjoining him, his agents, servants, employees, and attorneys, and all persons in active concert or participation with them, from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce a food, to wit, cherry juice, which is adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342 (a) (3) and (4).

Dated: \_\_\_\_\_,  
\_\_\_\_\_, 19\_\_\_\_.

\_\_\_\_\_  
Defendant

\_\_\_\_\_  
Attorney for Defendant







# INDEX

References are to page numbers.

## A

- Absorbent cotton . . . 620, 716, 732  
Acarus . . . 727  
Accompanying labeling—See also "Advertising as labeling"; "Labeling"; "Misleading"  
. . . Court of Appeals . . . 15, 122, 212, 332, 343, 388, 445, 521  
. . . District Court . . . 5, 64, 274, 315, 328, 443, 462, 463, 529  
. . . Supreme Court . . . 249, 382, 560  
Accurate statement of quantity of contents . . . 831, 833, 839  
Acetanilid . . . 574, 687, 708, 714, 834  
Acetic acid . . . 589  
Acetone . . . 725  
Acetophenetidin . . . 574, 644, 708, 714, 834  
Acetyl methyl carbinol . . . 618  
Aconite . . . 708, 713  
Acquittal, motion . . . 387  
Act, doing of any other . . . 319, 334, 350, 443, 445  
Actinomyces bovis . . . 759  
Action in personam  
. . . injunction . . . 59, 466  
Action in rem  
. . . injunction  
. . . . . portion of decree in rem . . . 466  
. . . seizure  
. . . . . Court of Appeals . . . 44, 122, 126  
. . . . . District Court . . . 2, 5, 8, 34, 51, 54, 59, 64, 89, 94, 511  
Activated ergosterol . . . 601  
Active ingredients . . . 642, 645, 697, 834  
Added caramel color . . . 647  
Added deleterious ingredient . . . 759  
Added poisonous or deleterious substance—See also "Poisonous substance"  
. . . 18, 310, 523, 759, 830  
Addition to food of economic adulterant—See also "Economic adulteration"  
. . . 830  
Adequate directions for use—See also "Directions for use" . . . 834  
Adequate warnings—See also "Warnings" . . . 834  
Administrative discretion in recommending prosecution . . . 278  
Administrative hearings . . . 543  
Administrative Procedure Act—See also "Food standards"  
. . . preparation of order . . . 543  
. . . separation of functions . . . 543  
. . . statement of policy . . . 543  
Administrator, Federal Security—See also "Food standards"; "Regulations"  
. . . authority . . . 477, 543  
. . . to promulgate regulations . . . 177, 289  
. . . definition in Act . . . 825  
. . . transfer of functions . . . 398  
Admiralty in seizure actions—See also "Action in rem" . . . 828  
. . . Court of Appeals . . . 44, 129  
. . . District Court . . . 26, 54, 482, 501, 505, 511, 521  
Adulterated products  
. . . cosmetics, when deemed to be . . . 838, 839  
. . . devices or drugs, when deemed to be . . . 833  
. . . food, when deemed to be . . . 830  
. . . introduction into interstate commerce prohibited . . . 826  
. . . manufacture of in territory prohibited . . . 826  
Adulteration—See also "Dangerous to health"; "Decomposed substance"; "Economic adulteration"; "Filth"; "Insanitary conditions"; "Unfit for food"  
. . . intended use of food immaterial . . . 135  
. . . not cured by truthful label . . . 135, 215, 477  
. . . time . . . 78, 135, 145  
Adulteration of product in interstate commerce prohibited . . . 826  
Adversely affected—See "Food standards"  
Advertising—See "Accompanying labeling"; "Directions for use"; "Federal Trade Commission"  
Advertising as labeling—See also "Labeling"  
. . . Court of Appeals . . . 15, 343  
. . . District Court . . . 462, 463, 529  
. . . Supreme Court . . . 382  
Advisory opinion . . . 477, 514  
Advisory standards . . . 543  
Affidavits submitted to jury . . . 318  
After shipment in interstate commerce—See "Interstate commerce"; "Seizure"  
Agar-Agar . . . 579, 696  
Agency—See also "Responsibility"  
. . . definition in Act . . . 825  
Agranulocytosis . . . 561  
Aid and abet . . . 278  
Aim of statute—See "Construction of Act"; "Purposes of Act"  
Albumen . . . 627  
Alcohol . . . 568, 617, 618, 620, 621, 623, 632, 650, 657, 681, 738, 830, 834  
Aldehydes . . . 618, 681  
Alfabeto . . . 583  
Alfalfa meal . . . 454  
Alimentary pastes . . . 583  
Alkaloids . . . 716, 717  
Alkanet root . . . 702  
Almond extract . . . 568  
Almond hand cream . . . 628  
Aloin . . . 744  
Alpha eucaine . . . 834



Alteration, etc., of labeling prohibited—  
     See also "Labeling" . . . . . 827

Ambiguous statements—See "Misleading"

American cheese . . . . . 678, 704

Amidopyrine . . . . . 834

Amino acids . . . . . 748

Aminopyrine . . . . . 561, 562, 633, 674, 698,  
     708, 713

Ammonia . . . . . 574, 577

Ammoniated mercury . . . . . 565, 674, 698

Ammonium carbonate . . . . . 588

Ampuling . . . . . 687

Ampuls . . . . . 581, 692, 745

Amyl acetate . . . . . 681

Analgesic . . . . . 689

Anchovies . . . . . 582, 585

Animal feeds . . . . . 682, 759

Anise extract . . . . . 569

Ankle supports . . . . . 611

Answer, forms . . . . . 856, 858

Answer, withdrawal of, form . . . . . 859

Antacids . . . . . 717

Anthelmintics . . . . . 574, 576, 604, 698, 708,  
     713, 729

Anthrax . . . . . 759

Anti-oxidants . . . . . 696

Antipasto . . . . . 583

Antipyrine . . . . . 577, 708, 714, 834

Antiseptic, representation as . . . . . 826

Any other act—See "Act, doing of any  
     other"

Any time thereafter—See "Interstate  
     commerce"; "Seizure"

Appeal—See also "Criminal procedure";  
     "Food standards"; "Rules of Civil  
     Procedure"

- . civil rules apply in appealed seizure  
     cases . . . . . 129, 193
- . denial of motion to permit reprocessing  
     is reviewable . . . . . 222
- . destruction of article renders question  
     moot . . . . . 191
- . error to exclude testimony of qualified  
     expert . . . . . 270
- . error with respect to portion of one  
     count . . . . . 270
- . failure to object or except . . . . . 303, 388
- . harmless error . . . . . 64, 197
- . judgment sustained if one charge  
     established . . . . . 107
- . lower court findings generally conclusive  
     107, 129, 134, 193
- . lower court findings not conclusive if  
     erroneous . . . . . 199
- . presumptions and inference in favor of  
     appellee . . . . . 370
- . refusal to postpone proceedings not  
     error . . . . . 518
- . rehearing . . . . . 129
- . trial court presumed to consider only  
     competent evidence . . . . . 370
- . trial court's order on reprocessing gen-  
     erally conclusive . . . . . 222
- . weight and credibility of evidence for  
     trier of facts . . . . . 370

Appear better or of greater value—See also  
     "Economic adulteration"  
     78, 135, 215, 412, 477, 830

Apples . . . . . 579

Applesauce, canned . . . . . 706

Applicators, wooden . . . . . 609

Apricots, canned . . . . . 649, 650

Argyrol . . . . . 564

Arnica . . . . . 575, 577

Aromatic cascara sagrada . . . . . 697

Arsenic . . . . . 577, 581, 586, 587, 622, 635, 674,  
     741, 834

Arsenic trioxide . . . . . 744

Arsphenamine . . . . . 719

Arthritis . . . . . 742

Artichokes . . . . . 582, 705

Articles . . . . . 134, 173, 179, 191

Artificial color . . . . . 568, 599, 634, 637, 647,  
     662, 831

Artificial flavor . . . . . 568, 611, 625, 636, 638,  
     660, 831

Artificial mustard oil . . . . . 660

Aspidium . . . . . 576, 698, 708, 714

Aspirin . . . . . 620, 746

Assorted candy . . . . . 663

Assorted chocolates . . . . . 663

Athlete's foot . . . . . 725

Atropine . . . . . 576, 718, 834

Attar of roses . . . . . 569

Attorney General . . . . . 477, 493

Aureomycin . . . . . 834, 837

Average consumer—See "Construction of  
     Act"; "Purposes of Act"

Avocados . . . . . 830

## B

Baby oil . . . . . 585

Bacillus anthracis . . . . . 759

Bacitracin . . . . . 834, 837

Baked goods . . . . . 578, 634, 645, 654

Bakery products . . . . . 578, 606, 607, 634, 645,  
     739

Bandages . . . . . 611, 733, 741, 757

Band-aid . . . . . 733

Barbiturates . . . . . 698, 713

Barbituric acid . . . . . 582, 834

Barley malt syrup . . . . . 657

Barley sugar . . . . . 584

Bay rum . . . . . 584, 738

Beans . . . . . 621, 622, 624, 635

Beans, with pork . . . . . 621, 623

Beer . . . . . 310, 657

Beets . . . . . 590

Belladonna . . . . . 717, 743

Benzaldehyde . . . . . 681

Benzedrine sulfate . . . . . 698, 708, 713

Benzoate of soda . . . . . 115, 145, 598, 599,  
     737

Benzyl benzoate . . . . . 727

Beriberi . . . . . 737

Beta-eucaine . . . . . 834

Beverage base . . . . . 653, 672

Beverages . . . . . 597, 631, 647  
     carbonated . . . . . 597, 672, 710

Bicarbonate of soda tablets, colored . . . . . 659

Bichloride of mercury . . . . . 565, 740

Bill of particulars—See "Discovery"

Birthday cake letters . . . . . 664

Bitter almond . . . . . 618



References are to page numbers.

- Black pepper oleoresin . . . 684  
 Blackleg . . . 760  
 Blank directions . . . 637  
 Bland . . . 744  
 Bleach cream . . . 565  
 Blended edible oils . . . 676  
 Blue ointment . . . 718  
 Blueberries, canned . . . 583, 584  
 Bond for release—See also "Condemnation and destruction"; "Release after condemnation"  
   . conditions and breach . . . 484, 490, 518  
   . exoneration, forms . . . 854  
   . form . . . 853  
   . motion for forfeiture . . . 484, 518  
   . penal and not indemnatory . . . 484, 490  
   . request for remission . . . 518  
 Bonito, canned . . . 758  
 Booklets—See "Accompanying labeling"; "Labeling"  
 Boric acid . . . 736  
 Bottles, labeling . . . 593  
 Bouillon, chicken . . . 621  
 Bovine actinomyces . . . 759  
 Bovine mastitis . . . 759  
 Bovine streptococcus agalactiae mastitis . . . 761  
 Box-end labels . . . 658  
 Bread . . . 605, 606, 607, 608, 634, 710, 737, 739  
 Brewers' yeast tablets . . . 738  
 Brick cheese . . . 564  
 Bromal . . . 834  
 Bromides . . . 577, 687, 703, 708, 713, 834  
 Broom tops . . . 707  
 Broth . . . 619  
 Brought into compliance—See also "Release after condemnation"  
   . . . 829  
 Brow tint . . . 149, 159, 161, 177, 564  
 Brown beauty beans . . . 635  
 Brushes . . . 612  
 Bucatini . . . 583  
 Buchu . . . 707  
 Bulk shipments . . . 99, 579, 584, 585, 591, 638, 718  
 Burden of proof—See also "Criminal procedure"  
   . criminal cases  
   . . beyond reasonable doubt  
   . . . Court of Appeals . . . 359, 370  
   . . . District Court . . . 253, 257, 289, 299, 306, 310, 526  
   . . not beyond all possible doubt . . . 370  
   . injunctions  
   . . administrative hearings . . . 543  
   . . preponderance of evidence . . . 463  
   . seizure cases  
   . . on Government . . . 54, 162, 173  
   . . preponderance of evidence . . . 2, 8, 30, 34, 89, 129  
 Burnt sugar coloring . . . 647  
 Butter . . . 156, 222, 449, 480, 526, 609, 636, 638, 639, 830, 831, 843  
 Butter Act . . . 846  
 Butter beans . . . 622  
 Butter cookies . . . 607  
 Butter crackers . . . 607  
 Butter cream loaf . . . 606  
 Butter flavored . . . 607  
 Butter-nut . . . 605  
 Butter wafers . . . 607  
 Buttermilk, condensed . . . 602  
  
**C**  
 Cacao products . . . 438  
 Caffeine . . . 625  
 Cajeput oil . . . 684  
 Cake decorations . . . 663, 664  
 Cake fruit fillers . . . 634, 680  
 Calcium citrate . . . 586, 587  
 Calcium compounds . . . 752  
 Calcium penicillin, veterinary use . . . 759  
 Calcium salts . . . 752  
 Calf diphtheria . . . 759  
 Calf pneumonia . . . 759  
 Calomel . . . 700, 711, 731  
 Camphor . . . 725  
 Camphor ice . . . 586  
 Canal Zone . . . 666  
 Candle holders . . . 664  
 Candy—See also "Confectionery"  
   . . . 294, 579, 584, 663, 664, 670, 694  
 Cane and malt syrup . . . 669  
 Cane syrup . . . 673  
 Cannabis . . . 834  
 Canned foods  
   . applesauce . . . 706  
   . apricots . . . 649, 656  
   . blueberries . . . 583  
   . bonito . . . 758  
   . carbon dioxide . . . 646  
   . clams . . . 710  
   . dog food . . . 679  
   . evaporated milk . . . 686  
   . field corn . . . 666  
   . fish roe . . . 651, 710  
   . fruit . . . 431, 686, 710  
   . fruit cocktail . . . 648  
   . fruit juices . . . 624  
   . grapefruit . . . 619  
   . grapefruit juice . . . 624  
   . huckleberries . . . 583  
   . labeling . . . 648, 672  
   . nitrogen . . . 646  
   . oysters . . . 710, 755  
   . peaches . . . 648, 649, 656, 661  
   . pears . . . 649, 656  
   . peas . . . 289, 673, 683, 695  
   . peppers . . . 703  
   . pimento . . . 703  
   . pinto beans . . . 635  
   . powders . . . 736  
   . prunes in syrup . . . 659  
   . Royal Anne cherries . . . 656  
   . salmon . . . 652  
   . shrimp . . . 652, 710  
   . soups . . . 686  
   . sweet potatoes . . . 697  
   . tomato juice . . . 680  
   . tomatoes . . . 592, 627, 688  
   . tuna . . . 652, 734, 758  
   . vegetables . . . 686, 710



- Cantaloupes . . . 830  
 Cantharides . . . 577, 708, 713  
 Cape Cod fillets . . . 670  
 Capsicum . . . 577  
 Capsules ovarian substance . . . 704  
 Caramel . . . 647  
 Caramel color . . . 572, 623, 647  
 Carbitol . . . 727, 734  
 Carbolic acid . . . 576, 741  
 Carbon dioxide, in canned foods . . . 646  
 Carbon tetrachloride . . . 576, 698, 708, 714,  
 Carbonated beverages . . . 597, 672, 710  
 Carbromal . . . 834  
 Cardio-vascular-renal disease . . . 762  
 Carnauba wax . . . 662  
 Carotene . . . 645  
 Carrier . . . 688, 841  
 Carrots and peas . . . 672  
 Cascara sagrada . . . 746  
 Cascarin . . . 699  
 Cassia cinnamon extract . . . 569  
 Cassia extract . . . 569  
 Castor oil . . . 575  
 Cat units, digitalis . . . 642, 692  
 Cathartics . . . 688  
 Catsup . . . 115, 145  
 Caustic lye dip . . . 660  
 Caution statements—See "Cosmetics"  
 Caviar . . . 651, 681  
 Cayenne pepper . . . 577, 661  
 Cease and desist order—See "Federal Trade  
 Commission"; "Res judicata"  
 Celebes coffee . . . 626  
 Celery, in broth . . . 619  
 Celery seed extract . . . 569  
 Cellosolve . . . 727  
 Cereal starches, salad dressings . . . 652  
 Certified food colors—See also "Coal-tar  
 colors" . . . 592  
 Ceylon cinnamon extract . . . 569  
 Chancroid . . . 711  
 Charcoal . . . 580  
 Charge to jury—See "Instructions to jury"  
 Cheddar cheese . . . 605, 662, 678  
 Cheese . . . 426, 564, 605, 630, 662, 678, 679,  
 704, 831  
 Chemical derivatives, habit forming . . . 834  
 Chemical preservative . . . 573, 582, 598,  
 636, 694, 736, 831  
 Chemicals, in foods . . . 589  
 Chenopodium oil . . . 577, 698, 708, 713  
 Cherries, maraschino . . . 644  
 Chewing gum . . . 595, 596, 830  
 Chicken bouillon . . . 621  
 Chicken flavoring . . . 619  
 Chicory . . . 584  
 Chili juice, with tomato juice . . . 612  
 Chili sauce, salad dressings . . . 652  
 Chisels . . . 631  
 Chloral . . . 834  
 Chloramphenicol . . . 834, 837  
 Chlorates . . . 577  
 Chlorobutanol . . . 698, 712, 725  
 Chloroform . . . 577, 617, 643, 698, 725, 834  
 Chlorophyll . . . 702  
 Chocolate . . . 638, 710  
 Chocolate flavored . . . 685  
 Chocolate ice cream . . . 671  
 Chopped fish . . . 681  
 Chrysarobin . . . 577, 708, 713  
 Chrysophanic acid . . . 708, 713  
 Cider vinegar . . . 695  
 Cinchona . . . 723, 728  
 Chinchonidine . . . 577  
 Cinchonine . . . 577  
 Cinchophen . . . 562, 633, 698, 708, 711, 713  
 Cinnamon . . . 618  
 Cinnamon extract . . . 569  
 Circulars—See "Accompanying labeling";  
 "Labeling"  
 Circulating cream . . . 566  
 Citrate of magnesia . . . 718  
 Citrates . . . 586, 587  
 Citric acid . . . 582, 586, 587, 618  
 Citrus fruits . . . 830  
 Civil rules—See "Appeal"; "Rules of civil  
 procedure"  
 Claim, form . . . 849  
 Claim, withdrawal of, form . . . 859  
 Clams, canned . . . 710  
 Clayton Act in contempt proceedings . . . 471  
 Clinical studies—See "Tests"  
 Clinical thermometers . . . 693  
 Clostridia . . . 759  
 Clostridium botulinum . . . 737  
 Clove . . . 569, 618, 689, 690  
 Club soda . . . 672  
 Coal-tar colors . . . 149, 159, 161, 177, 359,  
 610, 616, 632, 636, 640, 655, 667, 700,  
 701, 712, 828, 830, 832, 833, 835, 838;  
 842  
 Coal-tar hair dye . . . 563, 610, 838, 839  
 Coca . . . 834  
 Cocaine . . . 834  
 Code labeling, chemicals for technical  
 use . . . 614  
 Codein . . . 674, 834  
 Codein sulfate . . . 674  
 Codfish caviar . . . 681  
 Cod liver oil . . . 709  
 Coffee . . . 626  
 Coffee cream . . . 706  
 Coffee substitute . . . 51  
 Cola . . . 625  
 Colchicine . . . 708, 713  
 Colchicum . . . 708, 713  
 Cold preparations . . . 710, 713  
 Colds . . . 710  
 Collateral attack on regulations—See also  
 "Appeal"; "Food standards";  
 "Regulations" . . . 149, 161, 177,  
 289  
 Collector of Customs—See "Imports"; Sec-  
 retary of Treasury  
 Colon bacilli . . . 760  
 Colonic irrigator . . . 199, 529  
 Color added . . . 634  
 Color restorer, hair . . . 566, 734  
 Colored with caramel . . . 647  
 Coloring, artificial . . . 568, 599, 634, 647,  
 662, 831  
 Colors—See "Coal-tar colors"; "Vegetable  
 Colors"  
 Comb . . . 613



References are to page numbers.

- Commerce clause—See also "Interstate commerce"  
 . Court of Appeals . . . 44, 85, 334  
 . District Court . . . 34, 64, 257, 319  
 . Supreme Court . . . 337, 350  
 Commissioner of Food and Drugs . . . 477, 493  
 Common carrier . . . 688  
 Common or usual name—See also "Food standards"  
 . drug . . . 99, 359, 834  
 . food . . . 51, 398, 426, 543, 830, 831  
 Compacts . . . 593  
 Compliance, brought into—See also "Release after condemnation" . . . 829  
 Compound distilled vinegar . . . 590  
 Compound spirit of myrcia . . . 584  
 Concealment of damage or inferiority—See "Inferiority concealed"  
 Concentrated orange juice . . . 672  
 Concurrent jurisdiction—See "Jurisdiction"  
 Condemnation and destruction—See also "Bond for release"; "Release after condemnation"  
 . condemnation  
 . . decree, must precede release or destruction . . . 26, 173, 179, 480  
 . . decree, binding in suit for damages . . . 514  
 . . distinguished from destruction . . . 89, 173  
 . . entire shipment based on samples . . . 173, 179, 205  
 . . form of decree . . . 850  
 . . form vacating default decree . . . 861  
 . destruction  
 . . article's destruction renders case moot . . . 191  
 . . discretion of court . . . 50, 227  
 . . labeling, destruction does not make case moot . . . 122  
 Condensed buttermilk . . . 602  
 Confectionery—See also "Candy"  
 . 579, 580, 588, 615, 662, 663, 664, 665, 670, 694, 830  
 Confectionery, retail stores . . . 665  
 Conflict of Federal and state laws—See "Jurisdiction"  
 Consensus of medical opinion—See "Evidence"; "Opinion evidence"  
 Consent decree of condemnation, form . . . 850  
 Consent decree of injunction, form . . . 867  
 Consolidation—See "Removal"  
 Conspicuous labeling . . . 831, 833, 839  
 Constitutionality—See also "Commerce clause"; "Interstate commerce"  
 . adequacy of notice . . . 149, 159  
 . attack on regulations . . . 177  
 . delegation of legislative authority . . . 34  
 . definiteness and certainty . . . 34, 64, 257  
 . due process . . . 54, 149, 159, 161  
 . fair hearing . . . 496  
 Constitutionality—continued  
 . guaranty provision . . . 337  
 . inspection provision . . . 359  
 . jury trial . . . 44, 54  
 . search and seizure  
 . . Court of Appeals . . . 44, 126, 210, 359  
 . . District Court . . . 28, 34, 82, 207, 379  
 . separability clause . . . 843  
 Construction of Act—See also "Purposes of Act"; "Statutory construction"  
 . Act liberally construed  
 . . Court of Appeals . . . 15, 99, 129, 135, 227, 343, 370, 445  
 . . District Court . . . 34, 56, 64, 173, 179, 257, 315, 319, 328, 379, 462, 529  
 . . Supreme Court . . . 278, 350  
 . to promote or further purposes of Act  
 . . Court of Appeals . . . 126, 129, 227  
 . . District Court . . . 257, 319  
 . . Supreme Court . . . 278, 350, 382  
 Consumers—See "Construction of Act"; "Lay users"; "Purposes of Act"; "Self medication"  
 Container, deceptive—See "Deceptive package"  
 Containers . . . 579, 580, 587, 592, 667, 668, 677, 830, 833, 838  
 Contempt . . . 466, 471, 827  
 Contents of package, label statement . . . 831, 833, 839  
 Contour cream . . . 566  
 Controversy—See also "Food Standards" . . . 477, 514  
 Cooked in vegetable oil . . . 651  
 Cookies . . . 607  
 Corn . . . 666  
 Corn meal . . . 565  
 Corn oil . . . 676  
 Corn pads . . . 580  
 Corn removers . . . 580  
 Corn sugar . . . 567, 621, 622  
 Corn sugar, beans with pork . . . 621  
 Cornstarch . . . 705  
 Corporation, responsibility . . . 278  
 Corpus luteum . . . 721  
 Corynebacteria . . . 759  
 Cosmetics  
 . adulterated, when deemed to be . . . 838, 839  
 . arsenic and lead as cosmetic ingredients . . . 635  
 . baby oil as cosmetic . . . 585  
 . bay rum containing isopropyl alcohol for cosmetic purposes . . . 738  
 . camphor ice as cosmetic . . . 586  
 . caution statements  
 . . coal-tar hair dyes . . . 563  
 . . hydrogen peroxide sold as unit with coal-tar component . . . 610  
 . . none on hair dye of harmless uncertified coal-tar colors . . . 610  
 . cosmetic containers  
 . . powder, deceptive . . . 592  
 . . quantity of contents labeling . . . 668  
 . cuticle remover as cosmetic . . . 665  
 . declaration of quantity of contents . . . 580  
 . . cosmetic containers . . . 668



## Cosmetics—continued

- definition in Act . . . . 825
- deodorant powder as cosmetic . . . . 581
- depilatories as cosmetics . . . . 581
- dibutyl phthalate as solvent for  
  certified color . . . . 701
- glycols in skin preparations . . . . 734
- gum in hair lacquer . . . . 341
- labeling of cosmetics containing  
  perfume . . . . 665
- labeling statements on cases and  
  bottles . . . . 593
- mercurial preservatives in skin  
  preparations . . . . 740
- mercury compounds in bleach  
  preparations . . . . 565
- misbranded, when deemed to be . . . . 839
- misleading or deceptive names . . . . 566
  - Eau de Quinine . . . . 526
  - honey and almond hand cream . . . . 628
- paraphenylenediamine in brow tint  
  149, 159, 161, 177, 564
- processing in other  
  establishment . . . . 839
- quinine hair preparations . . . . 707
- shampoos and shaving creams as  
  cosmetics . . . . 625
- shampoo tints as hair dyes . . . . 666
- soap exempt from cosmetic provisions  
  625
- statement of contents of perfume . . . . 665
- sun tan preparations as cosmetics . . . . 593
- titanium dioxide as ingredient . . . . 581
- tonic hair preparations . . . . 707
- Costs . . . . 829
- Cottage cheese . . . . 679
- Cotton, absorbent . . . . 620, 716, 732
- Coughs, . . . . 577
- Coumarin . . . . 568, 618
- Counterclaim . . . . 54
- Crabmeat . . . . 669
- Crabs . . . . 718
- Cracked wheat bread . . . . 739
- Crackers, butter . . . . 607
- Cream . . . . 706
- Creamed cottage cheese . . . . 679
- Cresols . . . . 576
- Creosote . . . . 576
- Criminal contempt—See “Contempt”
- Criminal liability—See “Responsibility”
- Criminal procedure—See also “Appeal”;  
  Burden of proof”; “Indictment  
  and information”; “Verdicts”
  - error affecting portion of one count . . . . 270
  - error to submit affidavits to jury . . . . 318
  - motion for acquittal and new trial . . . . 387
  - revocation of probation . . . . 507
  - separate verdict on each count . . . . 359, 388

## Criminal procedure—continued

- separate verdict as to each  
  defendant . . . . 359, 388
- variance of charge and proof . . . . 537
- Crow’s-foot cream . . . . 566
- Crude drug . . . . 587
- Cryolite . . . . 440
- Cubeb oil . . . . 684
- Cudbear extract . . . . 702
- Customs—See “Imports”; “Secretary of  
  Treasury”
- Cut out syrups . . . . 656
- Cuticle remover . . . . 665

## D

- DDT . . . . 750
- Damage concealed—See “Inferiority  
  concealed”
- Damages
  - breach of warranty not issue in seizure  
  case . . . . 511
  - decree of condemnation binding in suit . . . . 514
- Dandruff . . . . 613
- Dangerous devices—See also “Dangerous  
  to health” . . . . 631
- Dangerous drugs—See “Dangerous to  
  health”; “Drugs”
- Dangerous to health—See also “Adultera-  
  tion”; “Decomposed substances”;  
  “Filth”; “Misleading”; “Unfit for  
  food” . . . . 830, 831, 833, 834, 838
  - cosmetics . . . . 149, 177
  - drugs . . . . 8, 22, 34, 53, 107, 448, 533, 590,  
  633, 698, 708, 713, 716, 727, 741, 742,  
  750
  - filthy article need not necessarily be  
  13, 59, 257, 451
  - shell fragments not ordinarily . . . . 18
- Deception—See “Deceptive package”;  
  “False and misleading”; “Mislead-  
  ing”
- Deceptive package—See also “Misleading”  
  171, 193, 247, 568, 592, 632, 831, 834, 839
- Declaration of contents . . . . 579, 580, 584,  
  585, 590
- Declaratory judgment . . . . 54, 477, 514
- Decomposed substance—See also “Adult-  
  eration”; “Filth” . . . . 830, 833,  
  838
  - article containing, need not be unfit  
  for food . . . . 110, 134, 225, 257, 306
  - fermentation . . . . 496
  - no excuse for, in food . . . . 179
  - percentage . . . . 13, 110, 134, 257, 306
  - water damage causing . . . . 496
- Decomposition—See also “Adulteration” . . . . 59
- Decree—See “Condemnation and destruc-  
  tion”; “Injunction”
- Deep pore cleanser . . . . 566
- Definition and standard of identity—See  
  “Food standards”
- Definitions of terms in Act . . . . 825
- Delegation of authority—See also “Consti-  
  tutionality”; “Regulations” . . . . 493



References are to page numbers.

- Deleterious ingredient, added—See “added deleterious ingredient”
- Deleterious substance—See “Added poisonous or deleterious substance”
- Deleterious to health—See “Dangerous to health”
- Deliver or proffer delivery . . . 826, 827
- De minimus rule—See “Filth”
- Denatured alcohol . . . 623
- Dental supplies . . . 671
- Deodorant . . . 581
- Depilatories . . . 566, 581
- Depositions—See “Discovery”
- Derivatives of drugs . . . 834
- Desserts . . . 616, 694, 705
- Destruction—See “Condemnation and destruction”
- Devices
- adulterated, when deemed to be . . . 833
  - classification of dental supplies . . . 671
  - comb labeled “For Dandruff and Scalp Infections” . . . 613
  - definition in Act . . . 825
  - directions for use . . . 714, 745
  - dosage directions . . . 714
  - false and misleading therapeutic claims
    - colonic irrigator . . . 199, 529
    - sinuothermic device . . . 212, 249, 521, 560
  - label information required on hot water bottles . . . 613
  - labeling requirements
    - clinical thermometers . . . 693
    - surgical instruments . . . 631
    - unsterile absorbent cotton . . . 716, 732
  - X-ray machines . . . 633, 700
  - manicuring instruments not devices . . . 613
  - misbranded, when deemed to be . . . 833, 834
  - misbranding of Spectro-Chrome when shipped in interstate commerce . . . 207, 210, 226, 365
  - misleading labeling of Electreat Mechanical Heart . . . 5
  - new drug section . . . 614
  - packaging requirement for gauze bandages . . . 757
  - razor blades not devices . . . 613
  - rubber nipples subject to Act depending on labeling claims . . . 614
  - rubber gloves for surgical use as therapeutic devices . . . 585
  - shipment of defective prophylactics in interstate commerce . . . 173, 205, 330
  - submission of applications to Administration . . . 613
  - supporters as devices . . . 611
  - suspensory bandages as devices . . . 611
  - syringe as device . . . 613
  - tongue depressors and wooden applicators as devices . . . 609
  - tooth brushes not therapeutic devices . . . 612
- Devices—continued
- unrestricted distribution of X-ray machines . . . 633
  - warnings, required . . . 690, 714
  - wrist bands as devices . . . 611
- Dextrose . . . 567, 621, 743, 746
- Diabetes . . . 388
- Diacetyl . . . 412
- Diagnosis—See “Lay users”; “Opinion evidence”; “Self-medication”
- Diagnostic preparations . . . 641
- Dibromoxymercurifluorescein sodium . . . 615
- Dibutyl phthalate . . . 701
- “Diced carrots and Alaska peas” . . . 672
- Dietary properties . . . 831
- Dietary uses of food . . . 831
- Diethylene glycol . . . 727, 734
- Diethylstilbestrol . . . 750
- Difference of medical opinion—See also “Evidence”; “Opinion evidence” . . . 826
- Digitalis . . . 578, 642, 692, 698, 714, 724, 728, 834
- Digitalis glucosides . . . 834
- Diglycol stearate . . . 625
- Dinitrocresol . . . 727
- Dinitrophenol . . . 727
- Directions for use—See also “Drugs” . . . 637, 643, 714, 719, 728, 745, 746, 747, 834
- exemption from hearing . . . 319, 529
  - for conditions advertised . . . 529, 533
  - inadequate . . . 53, 529
- Discetyl . . . 618
- Discovery . . . 28, 33, 212, 482, 501, 505, 521
- Diseased animals, product . . . 830
- Diseases—See “Skin Diseases”
- Disposition of condemned goods—See “Condemnation and destruction”; “Release after condemnation”
- Dissemination of information by Administrator . . . 842
- Distilled vinegar . . . 589, 590, 695
- Distilled water . . . 746
- Distributor . . . 668
- District of Columbia—See “Injunction”; “Jurisdiction”
- District of reasonable proximity—See “Removal”
- Diuretics . . . 707, 717
- Dog food, canned . . . 679
- Doing of any other act—See “Act, doing of any other”
- Douches . . . 574
- Dough conditioner . . . 607, 608
- Doughnuts . . . 739
- Dried products
- beans . . . 624
  - egg albumen . . . 578, 627
  - egg product, in confectionery . . . 615
  - egg white . . . 578
  - eggs . . . 578
  - fruits . . . 830
  - lentils . . . 624
  - peas . . . 624
  - prunes . . . 659
  - skim milk . . . 398, 403, 742



## Dried products—continued

- vegetables . . . 830
- whole eggs . . . 578
- Drills . . . 631
- Drug container, individual tube . . . 587
- Drug containers . . . 580, 587
- Druggist, exemption of prescription drugs . . . 835
- Drugs
  - actionable . . . 561, 562
  - active ingredients . . . 299, 359, 623, 642, 643, 645, 675, 697, 702
  - addition of substance to reduce quality or strength or in substitution . . . 833
  - adulterated, when deemed to be . . . 833
  - adulteration . . . 21, 253, 262, 359, 370, 473
  - agar-agar in candy . . . 579
  - antacid . . . 717
  - article offered for tonic action . . . 655
  - brand names . . . 582
  - calomel and petrolatum in ointment . . . 711
  - caution statement on narcotics . . . 659
  - certified colors in surgical sutures . . . 619
  - chlorobutanol as preservative . . . 712
  - classification of dental supplies . . . 671
  - coal-tar color . . . 667
  - cold preparations . . . 710
  - color in tablets . . . 659
  - crude . . . 587
  - dangerous . . . 561, 590, 633, 698, 708, 711, 713, 716, 727, 741, 742, 750
  - declaration of ingredients . . . 614, 617, 694, 697, 722
  - defined . . . 2, 8, 825
  - depilatories as drugs . . . 581
  - derivatives of hypnotics and narcotics . . . 674
  - diagnostic preparations . . . 641
  - directions for use . . . 533, 609, 639, 643, 691, 719, 724, 728, 743, 745, 746, 747
  - diuretic . . . 717
  - dosage . . . 733, 759
  - encapsulating operations . . . 611
  - estrogen in glandular preparation . . . 748
  - exemptions . . . 99, 604, 618, 637, 718, 725, 738
  - expectorant . . . 717
  - false guaranty . . . 337
  - false therapeutic claims . . . 50, 64, 141, 187, 197, 218, 227, 274, 299, 328, 343, 388, 443, 445, 463
  - foreign language labeling requirements . . . 684
  - habit forming . . . 591
  - inert ingredients . . . 574, 698, 704, 721, 756
  - ingredient statements . . . 587
    - use of chemical in lieu of trade name . . . 615
  - intended use . . . 8, 15, 22

## Drugs—continued

- lecithin as ingredient in cacao products . . . 438
- liable to deterioration . . . 834
- manner of labeling . . . 315, 493, 581, 639, 650, 674, 689, 692
- manufactured on physician's order . . . 604
- manufacturing use . . . 614
- method of packing . . . 834
- misbranded, when deemed to be . . . 833, 834
- misbranding . . . 21, 26, 89, 94, 122, 182, 253, 262, 382, 537
- misrepresentation as to source . . . 681
- monochloroacetic acid in stabilizer for soft drinks . . . 523
- name and quantity or proportion . . . 834, 845
- new . . . 436, 602, 608, 733, 759, 762, 835, 836
- nomenclature . . . 643, 674
- obesity remedy dangerous to health . . . 53
- potency declaration of digitalis preparation . . . 642, 692
- poultry remedy requirements . . . 731
- prescriptions . . . 604, 699, 708, 716, 720, 727, 741, 752
- processing, labeling, or repacking in further establishment . . . 835
- professional use . . . 604, 605
- rebottling of bulk drugs by pharmacist . . . 591
- sales without prescription . . . 319, 334, 350
- sample packages . . . 605
- shipment by physician . . . 640
- shipped to physician . . . 637
- sold under names of other drugs . . . 834
- strength, purity, or quality falling below that represented . . . 833
- sulfanilamide for veterinary use . . . 719
- sunburn preparation as drugs . . . 593
- tablet manufacture . . . 620
- thyroid in reducing preparation . . . 34, 107, 448
- tooth powder as drug . . . 659
- trade names . . . 582
- "until relieved" . . . 680
- use of amino acids . . . 748
- valueless in specific instances . . . 620, 707
- vitamins . . . 265, 285, 328, 742
- warnings . . . 562, 574, 591, 604, 629, 641, 658, 690, 696, 709, 729, 741, 743, 744, 752, 757, 759
- Due process . . . 54, 149, 159, 161
- Dulcin . . . 691
- Duplicity . . . 270, 537
- Dusting powder, antiseptic . . . 826
- Dye, hair and orbital area . . . 563, 564, 610, 666, 838, 839



References are to page numbers.

## E

- Earache drops . . . 747
- Economic adulteration—See also "Adulteration"; "Appear better or of greater value"; "Inferiority concealed" . . . 56, 115, 135, 145, 215, 419, 830
- Eczema—See "Skin diseases"
- Effective date of Act . . . 34, 843
- Efficacy—See "Misleading"; "Issue of fact"
- Egg albumen . . . 627
- Egg ingredients . . . 578
- Egg noodles . . . 619, 634
- Egg substances . . . 578
- Egg white . . . 578
- Egg yolk . . . 578
- Eggs . . . 48, 59, 85, 257, 578
- Eggs, declaration of in beverages . . . 631
- Elastic wrist bands . . . 611
- Elixir aminopyrine . . . 674
- Emergency permit control . . . 831
- Emetine . . . 708, 713
- Emulsifier . . . 438
- Enacting clause of Act . . . 825
- Encapsulating operations . . . 611
- Enlarged pore preparations . . . 566
- Enriched foods . . . 405, 419
- bread . . . 737
- doughnuts . . . 739
- flour . . . 739
- Epinephrine . . . 708, 713, 742
- Equine pneumonia . . . 760
- Ergosterol . . . 601
- Erigeron oil . . . 684
- Error—See "Appeal"; "Criminal procedure"
- Erysipelothrix rhusiopathiae . . . 760
- Esters . . . 681
- Estoppel by judgment—See "Res judicata"
- Estrogenic activities . . . 574
- Estrogenic extracts . . . 721
- Estrogens . . . 748
- Ether . . . 577, 681, 834
- Ethyl acetate . . . 681
- Ethyl alcohol . . . 568, 617, 738
- Ethyl oenanthe . . . 618
- Ethyl vanillin . . . 638
- Ethylene glycol . . . 727, 734
- Evaporated milk . . . 686, 710
- Evidence—See also "Food standards"; "Issue of fact"; "Lay users"; "Opinion evidence"; "Presumption of regularity"; "Tests"
- administrative hearings . . . 543
- difference of medical opinion . . . 64, 107, 197, 199, 212, 227
- experiments . . . 227
- financial loss . . . 89, 195
- fraud in seizure cases . . . 227
- identity of unstandardized food . . . 162
- illegality obtained . . . 379
- motion to suppress . . . 379
- no complaints about drug . . . 8, 463
- past sales . . . 8
- presumption of regularity . . . 370, 398, 543
- presumption that only competent evidence considered . . . 370

## Evidence—continued

- proof of one false claim  
        sufficient . . . 197, 199, 537, 560
- scientific testimony . . . 64, 94, 199, 212, 218, 227
- substantial, as basis for  
        finding . . . 496
- testimonials . . . 94, 270
- treatises . . . 94, 199, 463
- weight and credibility for trier  
        of facts . . . 370
- Examinations and investigations . . . 841
- Exceptions to libel—See "Libel"
- Exemptions—See also "Drugs"; "Guaranty"; "Regulations" . . . 603, 637, 831, 832, 833, 834, 835, 839
- bulk shipments . . . 99
- directions for use . . . 529, 533
- receipt and delivery . . . 341
- Exoneration of bond, forms . . . 854
- Expectorants . . . 717
- Experiments—See "Tests"
- Expert testimony—See "Opinion evidence"
- Export . . . 842, 843
- article offered for import . . . 496
- condemned article . . . 242, 513, 518
- injunction to enjoin . . . 496
- interpretation . . . 643
- Extract . . . 568
- Extract of aloe . . . 587
- Extracted honey . . . 686
- Eye wrinkle cream . . . 566
- Eyebrow dye . . . 564, 838
- Eyebrow tint . . . 149, 159, 161, 177
- Eyebrows . . . 838
- Eyelash dye . . . 564, 838
- Eyelash grower . . . 566
- Eyelashes . . . 838

## F

- Facial tissue . . . 585
- Factory inspection . . . 82, 126, 359, 379, 826, 842
- Failure to bear warnings . . . 94
- Failure to reveal consequences . . . 826
- Failure to reveal facts—See also  
    "Misleading" . . . 2, 5, 34, 107, 227, 370, 523
- False advertising—See "Federal Trade Commission"
- False and misleading—See also  
    "Misleading"
- cosmetics . . . 839
- devices . . . 173, 205, 833
- drugs . . . 833
- inefficacy . . . 2, 5, 8, 22, 53, 64, 94, 197, 227, 388
- meaning of labeling . . . 64, 94, 197, 299, 388
- safety . . . 34, 53, 107
- sufficiency of allegation . . . 15
- food . . . 831
- coffee substitute . . . 51
- name of unstandardized food . . . 162
- False teeth . . . 671
- "Fancy" . . . 686
- Farfalline . . . 583



- Farina . . . 405, 419
- Fatty acids, unsaturated . . . 611
- Federal Alcohol Administration Act . . . 657
- Federal Caustic Poison Act . . . 725
- Federal Rules of Civil Procedure—See “Rules of Civil Procedure”; “Appeal”
- Federal Security Agency—See also “Administrator” facilities . . . 227
- Federal Trade Commission—See also “Advertising as labeling”; “Res judicata”
- . action does not bar suit under Act 15, 22, 53, 122, 187, 462, 533
  - . control of advertising . . . 443, 445, 533
  - . decision res judicata . . . 80, 141, 182
  - . decision not res judicata . . . 187
- Feed . . . 682, 759
- Fees of Court . . . 829
- Fennel . . . 618
- Ferrous carbonate . . . 744
- Ferrous sulfate . . . 741
- Fettuccine . . . 583
- Field corn, canned . . . 666
- Fill of container—See “Deceptive package”; “Food standard”; “Standard of fill”
- Filled Cheese Act . . . 844
- Filled Milk Act . . . 419, 844
- Fillets of anchovies . . . 585
- Filth—See also “Adulteration”; “Insanitary conditions”
- . adverse conditions . . . 348, 449, 451
  - . aphix in spinach . . . 514
  - . construction of word “filth” . . . 306, 348, 449, 451
  - . deminimus rule . . . 222, 306
  - . fish viscera . . . 30
  - . injuriousness to health . . . 13, 59, 257, 451
  - . proportion . . . 294
  - . substantial . . . 222, 306
  - . tolerance . . . 179, 222, 451
  - . unattractiveness . . . 30
- Filthy, putrid, or decomposed substance . . . 830, 833, 838
- Financial loss—See “Evidence”
- Findings of fact—See also “Regulations”
- . injunction against Government . . . 493, 496
  - . injunction to enjoin violations . . . 449, 456, 463, 473
  - . new drug application . . . 436
  - . seizure . . . 218, 523, 529
- Fines—See “Penalties”
- Finger bandages, sulfathiazole . . . 733
- First grade . . . 732
- Fish . . . 30, 110, 134, 238, 585, 653, 670, 681
- Fish, sodium nitrite . . . 652
- Fish liver oils . . . 601, 645
- Fish roe, canned . . . 651, 710
- Fixatives, fruit flavors . . . 625
- Flavor . . . 568, 611
- Flavoring compounds, coal-tar colors . . . 636, 655
- Flavoring extracts, confectionery . . . 830
- Flavorings . . . 568, 600, 611, 618, 619, 636, 638, 639, 655, 660, 677, 681, 689, 720, 831
- Flour
- . enriched . . . 739
  - . use of guaranty statements . . . 646
- Flour products . . . 405, 419
- Fluid extract of gentian . . . 587
- Fluorine . . . 310, 440, 622
- Food
- . acetic acid in foods . . . 589
  - . adulterated, when deemed to be . . . 830
  - . ambiguity of “prune” . . . 659
  - . amino acid in foods . . . 748
  - . ammonium carbonate in confectionery . . . 588
  - . anti-oxidants in salad oils . . . 696
  - . antipasto as common name of product . . . 583
  - . aphix in spinach . . . 514
  - . artificial color in canned peas . . . 673
  - . artificial color in process cheese . . . 662
  - . artificial color in tomato products . . . 637
  - . benzoate of soda in tomato catsup . . . 115, 145
  - . box-end labels . . . 658
  - . brand designations on canned fruits and vegetables . . . 686
  - . bulk shipments of swordfish . . . 639
  - . Butter Cream Loaf bread . . . 606
  - . butter in baked goods . . . 607
  - . butterfat content of ice cream mix . . . 600
  - . “Butter-Nut bread . . . 605
  - . caffeine in soft drinks . . . 625
  - . caramel as artificial color . . . 647
  - . carotene in soybean flour . . . 645
  - . charcoal in confectionery . . . 580
  - . chemicals in foods . . . 589
  - . chocolate flavored with vanillin . . . 638
  - . chopped fish in sausage casing . . . 681
  - . citric acid in artichokes . . . 582
  - . citric acid in foods . . . 586
  - . coal-tar color in foods . . . 616
  - . cocoa in ice cream . . . 671
  - . common or usual name . . . 51
  - . containers for fresh fruits and vegetables . . . 677
  - . cottonseed oil as packing medium . . . 734
  - . declaration of artificial color . . . 599
  - . declaration of meat by-products in canned dog food . . . 679
  - . declaration of preservative in ice cream . . . 598
  - . definition . . . 2, 825
  - . designation of mint tea . . . 623
  - . designation of size of canned peas . . . 695
  - . dietary supplement in wine base . . . 725



References are to page numbers.

## Food—continued

- . diglycol stearate in food . . . . 625
- . dried egg product in confectionery . . . . 615
- . dulcin in food . . . . 691
- . exemption from Act . . . . 665
- . exemptions from ingredient statement . . . . 564, 596, 597, 616, 647, 704, 710
- . exemptions from net weight statement . . . . 584, 653
- . expression of vitamin content . . . . 607
- . fabricated from more than one ingredient . . . . 831
- . fixatives in pure fruit flavors . . . . 625
- . flavoring in broth . . . . 619
- . foreign language on label . . . . 628
- . "fresh" as applied to butter . . . . 609
- . "fresh" on canned foods . . . . 680
- . fumigant in food . . . . 648
- . glycerin in peanut butter . . . . 641
- . grenadine in fruit syrup . . . . 684
- . guaranty statements on flour . . . . 646
- . hexamethylenetetramine in cod fish caviar . . . . 681
- . home made . . . . 630
- . honey in bread . . . . 605
- . importation of pineapple products . . . . 746
- . individually wrapped bakery products . . . . 645
- . invert sugar in cane and maple syrups . . . . 669
- . iron in bakery products . . . . 739
- . Java-Mocha blend coffee . . . . 626
- . label arrangement for pork and beans . . . . 623
- . labeling
  - . . . alimentary pastes . . . . 583
  - . . . anchovies . . . . 585
  - . . . assorted chocolates . . . . 663
  - . . . assorted nuts . . . . 685
  - . . . butter . . . . 638
  - . . . canned broken grapefruit . . . . 619
  - . . . canned field corn . . . . 666
  - . . . caviar . . . . 651
  - . . . chicken bouillon . . . . 621
  - . . . dried vegetables . . . . 624
  - . . . feed . . . . 682
  - . . . fish . . . . 670
  - . . . flavors . . . . 655
  - . . . frozen foods . . . . 600
  - . . . goose liver paste . . . . 588
  - . . . honey . . . . 626, 686
  - . . . huckleberries . . . . 583
  - . . . ice cream . . . . 599
  - . . . ice cream carton . . . . 608
  - . . . imitation flavors . . . . 618
  - . . . maraschino cherries . . . . 644
  - . . . mixture of distilled and cider vinegar . . . . 695
  - . . . mixture of two standardized vegetables . . . . 672
  - . . . mustard . . . . 660
  - . . . olive oil . . . . 649
  - . . . oysters . . . . 673
  - . . . peanuts . . . . 756
  - . . . pectin preparations . . . . 657

## Food—continued

- . label arrangement—continued
  - . . . pinto beans . . . . 635
  - . . . potato chips . . . . 651
  - . . . potatoes in sacks . . . . 654
  - . . . round food cans . . . . 648
  - . . . sugar cane syrup . . . . 673
  - . . . tea bags in retail carton . . . . 609
  - . . . tomato products . . . . 592, 612, 627, 683, 688, 690
  - . . . unwrapped bakery products . . . . 634
  - . . . vitamin-carrying oil . . . . 692
- . labeling requirements of undrawn poultry . . . . 629
- . lemon emulsion in pie or cake . . . . 619
- . lima beans labeled as "Butter Beans" . . . . 622
- . liquid packed medium for canned fruits . . . . 649
- . "milk fed" poultry . . . . 629
- . mineral oil coating on apples . . . . 579
- . mineral oil in food . . . . 735
- . mineral oil in salad dressing . . . . 730, 752
- . mineral oil in popcorn dressing . . . . 56, 215
- . misbranded products . . . . 162, 171, 245, 367, 454, 456, 521, 526, 640, 683
- . misbranded, when deemed to be . . . . 831
- . moisture content of cheese . . . . 426
- . monochloroacetic acid in beverage base . . . . 523
- . monochloroacetic acid in beverages . . . . 751
- . monochloroacetic acid in food product . . . . 721
- . monosodium glutamate as artificial flavor . . . . 660
- . monosodium glutamate in foods . . . . 762
- . monosodium glutamate in soups . . . . 703
- . net weight statement on containers of fish . . . . 582
- . neutralizer in cream . . . . 636
- . niacin in bakery products . . . . 739
- . nitrogen or carbon dioxide in canned foods . . . . 646
- . nomenclature of artichokes . . . . 705
- . nomenclature of bonito . . . . 758
- . nomenclature of cream . . . . 706
- . nomenclature of sweet potatoes . . . . 697
- . nonexemption of raw materials . . . . 603
- . packaging of gelatin dessert . . . . 694
- . packing of canned oysters . . . . 755
- . pantothenic acid in yeast tablets . . . . 738
- . para-aminobenzoic acid as food essential . . . . 734
- . plain wrapped cheese . . . . 678
- . processing, labeling, or repacking in further establishment . . . . 832
- . propylene glycol in food products . . . . 720
- . pumpkin in baked goods . . . . 654



## Food—continued

- "pure" on food labels . . . 589
- pyridoxine in yeast tablets . . . 738
- quantity of contents declaration
  - liquid soups . . . 686
  - pickles . . . 661
- reconditioning of adulterated product . . . 195
- resinous glaze in confectionery . . . 662
- riboflavin in bakery products . . . 739
- riboflavin in milk . . . 602
- saccharin in food . . . 691, 724
- salt and citric acid in crabmeat . . . 669
- salt as food . . . 676
- same article constituting drug . . . 2, 265, 630
- sandwich cuts of Swiss cheese . . . 630
- saponin in beverages . . . 647
- seeds in canned pimentos . . . 703
- shell fragments in oysters . . . 18
- shortening and leavening ingredient in bakery products . . . 607
- Silver Dragees on confectionery . . . 663
- sirups in canned fruits . . . 656
- slack-filling of candy . . . 193, 247
- slack-filling of gelatin packages . . . 632
- sodium bisulphite in candy . . . 664, 694
- sodium carbonate in pretzels . . . 660
- sodium nitrite in fish fillets . . . 652
- solid pack . . . 627, 661
- specific starches in salad dressing . . . 689
- standard of fill for oysters . . . 543
- standard of identity for oleomargarine . . . 412
- starch in standardized food . . . 705
- statement of ingredients
  - applesauce, canned . . . 706
  - beans, canned . . . 621
  - chewing gum . . . 595
  - eggs in bakery products . . . 578
  - imitation strawberry jam . . . 712
  - macaroni products . . . 634
  - marmalade . . . 704
  - mincemeat . . . 654
  - peanut butter sandwich . . . 666
  - process cheese . . . 678
  - shortenings . . . 594
  - spice flavorings . . . 689
  - vitamin capsules or tablets . . . 726
- status of cake decorations . . . 664
- status of raw sugar . . . 675
- sweetening ingredient in canned grapefruit juice . . . 624
- synthetic vanillin in ice cream . . . 600
- thiamine in bakery products . . . 739
- toxic substances in animal feeds . . . 759
- U.S. Grade A . . . 603
- vanilla in food products . . . 677
- vignettes on labels . . . 652
- vinegar in sauerkraut . . . 736
- vitamin B complex . . . 715

## Food—continued

- vitamin content of food products . . . 607
- vitamin D in farina . . . 405, 419
- vitamin E in wheat germ oil . . . 723
- vitamins as food . . . 265
- vitamins for poultry feeding . . . 709
- vitamins in sweet chocolate . . . 509
- water and butterfat in process cheese . . . 605
- water in bread . . . 606
- wrappers on fruit and vegetables . . . 680
- zucca melon in fruit cake . . . 680
- Food and Drugs Act . . . 13, 34, 44, 64, 115, 134, 189, 227
- Food color added . . . 634
- Food colors . . . 592
- Food standards—See also "Administrative Procedure Act"; "Administrator, Federal Security"; "Appeal"; "Imitation"; "Regulations"; 830, 831, 839, 840
  - Administrator, authority . . . 477, 543
  - adversely affected . . . 395, 412, 431, 438, 440
  - advisory standard, effect of . . . 543
  - burden of proof . . . 543
  - butter, statutory standard . . . 526
  - collateral attack . . . 289
  - common or usual name . . . 51, 398, 426, 543, 830, 831
  - controversy . . . 395, 412, 431, 438, 477, 514
  - evidence
    - hearsay . . . 543
    - removal for further . . . 543
    - substantial . . . 395, 419, 496, 543
    - tabulations . . . 543
  - fill of container . . . 543
  - findings
    - negative . . . 395
    - required . . . 395, 398, 403
    - supplementary . . . 403, 543
  - hearing, refusal to hold . . . 509
  - imitations as affected by standard . . . 412
  - ingredients, adding those not permitted by standard . . . 115, 145
  - ingredients, excluding wholesome . . . 419
  - labeling of optional . . . 438
  - notice of hearing . . . 405, 419, 543
  - other statutory requirements as affected . . . 412
  - purport to be . . . 115, 145, 245
  - purpose . . . 395, 398, 405, 419
  - quasi-legislative power . . . 398
  - record, consideration of entire . . . 543
  - removal for further evidence . . . 543
  - review
    - matters not raised at hearing . . . 543
    - scope . . . 395, 398, 412, 419, 426, 543
  - rule-making . . . 543
  - selectivity in adopting . . . 215, 398
  - unstandardized food, identity . . . 162, 215
  - violation . . . 115, 145, 245



## Index

References are to page numbers.

- Forceps . . . 631  
 Forging of identification device . . . 827  
 Forms  
   . answer . . . 856, 858  
   . bond . . . 853  
   . claim . . . 849  
   . consent decree of  
     condemnation . . . 850  
   . consent decree of injunction . . . 867  
   . interrogatories . . . 866  
   . motion to vacate default decree,  
     and order . . . 861, 862, 863  
   . order accelerating return of  
     monition . . . 857  
   . order permitting withdrawal of claim  
     and answer . . . 859  
   . petition for exoneration of bond, and  
     order . . . 854, 855  
   . stipulation consolidating and removing  
     seizure action, and order . . . 864,  
       865  
 Formulary—See "Official compendium"  
 Fraud order . . . 5  
 Freckles . . . 565  
 Fresh fruits . . . 658, 677, 830, 832  
 Fresh fruits and vegetables, copy of  
   Government's analysis . . . 829  
 Fresh tomato juice . . . 680  
 Fresh vegetables . . . 658, 677, 830, 832  
 Fried in vegetable oil . . . 651  
 Frozen fresh . . . 600  
 Frozen products  
   . custard . . . 596, 710  
   . desserts . . . 596, 599  
   . ingredient statement . . . 616  
   . egg white . . . 578  
   . egg yolk . . . 578  
   . eggs . . . 578  
   . fillets . . . 670  
   . fish . . . 670  
   . foods, labeling . . . 600  
   . swordfish . . . 639  
   . whole eggs . . . 578  
 Fructose syrup . . . 649, 650  
 Fruit  
   . canned . . . 431, 686, 710  
   . citrus . . . 830  
   . dried . . . 830  
   . fresh . . . 658, 677, 830, 832  
 Fruit cake . . . 680  
 Fruit cocktail, canned . . . 648  
 Fruit fillers, bakery products . . . 634  
 Fruit flavors . . . 568, 598, 625  
 Fruit ice cream . . . 598  
 Fruit juices, canned . . . 624  
 Fruit preserves . . . 647, 710  
 Fruit syrups . . . 568  
 Fruit wrappers . . . 680  
 Full strength . . . 600  
 Fumigant, in food . . . 648
- G**
- Gall bladder . . . 463  
 Gauze bandages—See also "Bandages"  
   . . . 757  
 Gelatin . . . 632, 655, 694  
 Gelsemium . . . 713
- General purpose . . . 716  
 Gentian, fluid extract . . . 587  
 Germicide . . . 826  
 Ginger extract . . . 569  
 Glacial acetic acid . . . 589  
 Glandular materials . . . 704  
 Glandular preparations . . . 574, 721, 747,  
   748, 756  
 Globe artichoke . . . 705  
 Glutamate, monosodium . . . 660, 703, 762  
 Glycerin . . . 568, 617, 727, 734  
   . addition to peanut butter . . . 641  
 Glycerol . . . 618  
 Glycols . . . 727, 734  
 Goa powder . . . 577, 708, 713  
 Gonorrhea . . . 711  
 Good faith—See also "Intent" . . . 827  
 Good manufacturing practice, poisonous  
   ingredient . . . 832  
 Goose liver paste . . . 588  
 Grade A . . . 603  
 Gram-negative bacilli . . . 760  
 Granulated chicken bouillon . . . 621  
 Granuloma inguinale . . . 711  
 Grape soda, imitation . . . 636  
 Grapefruit, canned . . . 619  
 Grapefruit juice, canned . . . 624  
 Greater value—See "Appear better or of  
   greater value"  
 Grenadine . . . 684  
 Guaicol . . . 575, 576  
 Guaranteed flour . . . 646  
 Guaranty . . . 646, 746, 826, 827  
   . agent's authority to give . . . 265  
   . attaches to intrastate  
     shipment . . . 337  
   . effect on criminal  
     responsibility . . . 262, 278  
   . innocent dealer protected . . . 367  
   . processor not protected . . . 330  
   . prosecution for giving false  
     guaranty . . . 285, 337  
 Guaranty statements . . . 573, 646  
 Gum . . . 341, 595, 596, 830  
 Gum benzoin . . . 584
- H**
- Habit-forming . . . 591, 834  
 Hair preparations  
   . color restorer . . . 566, 734  
   . dyes . . . 563, 610, 666, 838, 839  
   . grower . . . 566  
   . lacquer . . . 341  
   . lotion . . . 665  
   . quinine . . . 707  
   . restorer . . . 566  
   . revitalizing preparations . . . 567  
   . tonics . . . 655, 707  
 Hand cream, honey and almond . . . 628  
 Handi-Tape . . . 733  
 Harmless coloring, confectionery . . . 830  
 Harmless error—See "Appeal"  
 Harmless flavoring,  
   confectionery . . . 830  
 Harmless resinous glaze,  
   confectionery . . . 830



Hawaii . . . 666  
 Healthful . . . 659  
 Hearing before prosecution . . . 257, 262, 275, 278, 829  
 Hearings . . . 839  
 Heavy cream . . . 706  
 Heavy whipping cream . . . 706  
 Held for sale . . . 64, 319, 334, 350, 382, 443, 445  
 Heliotropin . . . 570, 618  
 Herbal laxatives . . . 580  
 Heroin . . . 834  
 Herring tidbits . . . 582  
 Hexamethylenetetramine . . . 681  
 High quality . . . 732  
 Holding company . . . 668  
 Home canning, preserving powders . . . 736  
 Home made . . . 630  
 Homoeopathic Pharmacopoeia . . . 833, 834  
 Honesty and fair dealing, definitions and standards for food . . . 830  
 Honey . . . 626, 686  
 Honey and almond hand cream . . . 628  
 Honey bread . . . 605  
 Horseradish . . . 699  
 Horseradish and beets . . . 590  
 Hot water bottle . . . 613  
 Household rubber gloves . . . 585  
 Huckleberries . . . 583  
 Hydrogen peroxide . . . 610  
 Hyoscine . . . 834  
 Hyoscyamine . . . 576, 834  
 Hypnotics . . . 674, 834  
 Hypodermic tablets, small containers . . . 659  
 Hypophosphites . . . 643  
 Hypothetical questions—See "Opinion evidence"

## I

Ice cream . . . 596, 598, 599, 600, 608, 671, 682, 710, 831  
 Ice cream powder . . . 682  
 Ice milk . . . 596, 710  
 Ice sherbet . . . 596, 599, 710  
 Ices . . . 596, 599  
 Identification device, forging . . . 827  
 Identity, definitions and standards of—See "Food standards"  
 Imitations—See also "Food standards" 89, 245, 412, 831, 834  
   flavors . . . 572, 618, 681  
   fruit . . . 568  
   vanilla . . . 638, 677  
   fruit syrups . . . 568  
   grape soda . . . 636  
   pineapple preserves . . . 746  
   prepared mustard . . . 660  
   strawberry jam . . . 712  
   tomato puree . . . 627, 640  
 Immediate container . . . 587  
   definition in Act . . . 826  
 Import Milk Act . . . 602, 844  
 Import procedure . . . 617, 649  
 Imports . . . 238, 496, 643, 842, 843

In personam—See "Action in personam"  
 In rem—See "Action in rem"  
 Inadequate directions for use—See "Directions for use"  
 Indictment and information — See also "Criminal procedure"  
   affidavits, submission of to jury is error . . . 318  
   duplicity . . . 270, 537  
   first offense may be prosecuted by information . . . 343, 382  
   same offense in separate counts . . . 285  
 Industrial use . . . 614  
 Inert ingredients . . . 574, 697, 704, 721, 756  
 Inferiority concealed—See also "Economic adulteration" . . . 56, 78, 135, 215, 830  
 Information—See "Indictment and information"  
 Information acquired under authority of Act . . . 827  
 Information, dissemination of by Administrator . . . 842  
 Inhalants . . . 576  
 Inhibitory use, antiseptic . . . 826  
 Injections . . . 745, 747  
 Injunction . . . 827  
   against Government . . . 493, 496  
   alleging prior criminal proceedings . . . 454  
   consolidation with seizure . . . 59  
   contempt procedure . . . 466, 471  
   decree  
   . . . form . . . 867  
   . . . in rem and in personam . . . 59, 466  
   . . . modification permitted . . . 468  
   . . . motion to set aside . . . 475  
   . . . nunc pro tunc . . . 463  
   . . . persons bound . . . 463, 466  
   . . . to enjoin violations only . . . 468  
   District of Columbia . . . 460  
   export, to enjoin order . . . 496  
   findings of fact . . . 456, 463, 473  
   intent not necessary . . . 451, 473  
   interstate business, amount of small . . . 451  
   motion to set aside . . . 475  
   purpose  
   . . . prevent deception . . . 456  
   . . . preventive remedy and not penal . . . 468  
   . . . strong probability of continued violations . . . 473  
 Injurious to health—See also "Cosmetics"; "Dangerous to health"; "Filth" 830, 833, 838  
 Insanitary conditions—See also "Adulteration"; "Filth" . . . 294, 830, 833, 838  
 Insecticidal residue—See "Spray residue"  
 Inspection—See also "Factory inspection"; "Records of interstate shipment"  
   consitutional provision . . . 359  
   sea food . . . 841



References are to page numbers.

Instructions to jury—See also "Jury"  
 . criminal cases . . . 253, 299, 306, 310, 526  
 . seizure cases . . . 2, 89  
 . trial judge instructs himself . . . 289  
 . viewed as a whole . . . 388  
 Insulin . . . 834, 837  
 Intent  
 . criminal cases  
 . . . Court of Appeals . . . 262, 270, 275, 341, 365, 388  
 . . . District Court . . . 253, 265, 299, 306, 310, 348, 526  
 . . . Supreme Court . . . 278  
 . injunction cases  
 . . . District Court . . . 451, 473  
 . seizure cases  
 . . . Court of Appeals . . . 126, 135, 187, 227  
 . . . District Court . . . 2, 5, 8, 59, 94, 122, 245  
 Intent of statute—See "Construction of Act"; "Purposes of Act"  
 Interpretation of statute—See "Construction of Act"; "Purposes of Act"  
 Interpretive regulations—See "Regulations"  
 Interrogatories—See also "Discovery"  
 . form . . . 866  
 Interstate commerce—See also "Commerce clause"  
 . adulteration after shipment . . . 189  
 . affecting . . . 64, 334  
 . after shipment . . . 64, 189, 319, 334, 350, 382, 443, 445  
 . any time thereafter . . . 156, 210  
 . definition in Act . . . 825  
 . district of Columbia . . . 460  
 . guaranty as to intrastate shipment . . . 337  
 . imported articles . . . 238  
 . introduction into . . . 59, 85, 99, 285, 341  
 . prevention of proscribed articles moving in . . . 59, 85, 134, 249  
 . receipt and delivery . . . 334  
 . records of interstate shipment . . . 82, 126, 359, 379  
 Interstate shipment—See "Records of interstate shipment"  
 Intravenous solutions . . . 743  
 Introduction into interstate commerce of adulterated or misbranded product prohibited . . . 826  
 Introduction into interstate commerce of article violating § 404 or 505 prohibited . . . 826  
 Invert sugar . . . 682  
 Investigations . . . 841  
 Iodides . . . 576, 702  
 Iodine . . . 576, 609  
 Ipecac . . . 708  
 Iron . . . 739, 741, 744  
 Iron cacodylate . . . 674  
 Irritants . . . 575, 577  
 Isinglass . . . 579  
 Isopropyl alcohol . . . 617, 620, 632, 650, 738

Issue of fact  
 . danger to health . . . 34  
 . device, efficacy . . . 365  
 . drug, efficacy . . . 64, 197, 199, 227, 388, 463  
 . meaning of labeling . . . 64, 94, 197, 388  
 . responsibility of individual . . . 359, 388  
 . slack-fill . . . 193  
 Italian, label information . . . 583  
 Italian style peeled tomatoes . . . 683

## J

Jalap . . . 697  
 Jam, imitation strawberry . . . 712  
 Java coffee . . . 626  
 Java-Mocha blend coffee . . . 626  
 Jerusalem artichoke . . . 705  
 Jobbers . . . 78  
 Judicial notice of chemistry . . . 440  
 Jurisdiction  
 . between state and federal laws . . . 334, 350  
 . breach of warranty as issue in seizure case . . . 511, 514  
 . federal law applies in District of Columbia . . . 460  
 Jury—See also "Instructions to jury"; "Verdict"  
 . affidavits submitted . . . 318  
 . manner of reaching verdict . . . 278  
 Jury trial . . . 44, 54, 828

## K

Kamala, use for poultry . . . 620  
 Katsuwonus pelamis . . . 758  
 Kerosene . . . 577  
 Ketchup—See "Catsup"  
 Ketones . . . 618, 681  
 Knives . . . 631  
 Knowledge and intent—See "Intent"

## L

Label—See also "Accompanying labeling"; "False and misleading"; "Labeling"; "Misleading"  
 . bulk shipments, requirements of as applied to . . . 99  
 . definition in Act . . . 826  
 . function . . . 99, 350  
 . labeling distinguished . . . 537  
 Labeling—See also "Accompanying labeling"; "Advertising as labeling"; "False and misleading"; "Label"; "Misleading"  
 . adulteration not cured by truth . . . 135, 215  
 . alteration . . . 827  
 . conspicuousness of information . . . 831, 833, 839  
 . definition in Act . . . 826  
 . food standard violation not cured by truth . . . 115, 145  
 . label distinguished . . . 537



## Labeling—continued

- . meaning
  - . . . Court of Appeals . . . 197, 199, 227
  - . . . District Court . . . 5, 64, 94, 218, 253, 274, 299
- . withdrawal does not render misleading labeling question moot . . . 122
- Labeling of cosmetic in further establishment . . . 839
- Labeling of drug in further establishment . . . 835
- Labeling of food in further establishment . . . 832
- Lasagne . . . 583
- Lasagnini . . . 583
- Laxative . . . 575, 580, 644, 691, 696, 709, 713, 744
- Laxative cold capsules . . . 713
- Lay users—See also "Self-medication" . . . 2, 34, 94, 207, 210, 212, 299
- Lead . . . 581, 586, 622, 635
- Leather wrist bands . . . 611
- Leavening ingredients . . . 607
- Lecithin . . . 438
  - . shortenings . . . 610
- Lemon cake . . . 619
- Lemon emulsion . . . 619
- Lemon extract . . . 568, 710
- Lemon flavor . . . 568, 569, 639
- Lemon pie . . . 619
- Lentils, dried . . . 624
- Leptosira . . . 760
- Leptospirosis . . . 760
- Liability for crimes—See "Responsibility"
- Libel
  - . affidavit not necessary . . . 34
  - . amending . . . 64
  - . amending to injunction . . . 59
  - . counterclaim . . . 54
  - . exceptions . . . 15, 54
  - . form . . . 15, 44, 51
  - . need not be verified . . . 44
  - . proceedings in connection . . . 828, 829
- Liberal construction—See "Construction of Act"
- Light cream . . . 706
- Light whipping cream . . . 706
- Lima beans . . . 622
- Limburger cheese . . . 564
- Liquid products
  - . egg white . . . 578
  - . egg yolk . . . 578
  - . eggs . . . 578
  - . extract of liver . . . 720
  - . foods . . . 686
  - . sugar . . . 682
  - . whole eggs . . . 578
- Lithium chloride . . . 762
- Liver preparations . . . 720
- Lollipops, with aspirin . . . 620
- Lotion, hair . . . 665
- Luminal . . . 582
- Lye dip, caustic . . . 660
- Lymphogranuloma inguinale . . . 711

## M

- Macaroni products . . . 634
- Magnesium carbonate . . . 564
- Magnesium citrate . . . 718
- Malaria . . . 728
- Malaria preparations . . . 723, 733
- Male fern . . . 576, 708, 714
- Malignant edema . . . 760
- Mallets . . . 631
- Malt syrup . . . 657
- Malted cereal . . . 657
- Malted cereal syrup . . . 657
- Malted milk . . . 685, 710
- Mammary . . . 721
- Mandamus . . . 480
- Manicuring instruments . . . 613
- Manufacturer . . . 668
- Manufacturing . . . 687
- Maple flavor . . . 618
- Maple syrup . . . 669
- Maraschino cherries . . . 644
- Marihuana . . . 834
- Marjoram extract . . . 570
- Marmalade . . . 647, 704
- Mastitis . . . 759, 760
- May . . . 34
- Mayonnaise . . . 598, 652, 696, 710, 730
- Meat . . . 843, 844
- Meat Inspection Act . . . 844
- Medical books—See "Evidence"
- Medical opinion—See "Opinion evidence"
- Medicinal soap . . . 675
- Medicinal tablets, use of isopropyl alcohol . . . 620
- Melons . . . 830
  - . Zucca . . . 680
- Mens rea—See "Intent"
- Menstrual pains . . . 689
- Menstruation . . . 689
- Menstruums . . . 568
- Menthol . . . 722
- Mercurial lipoid . . . 694
- Mercurial ointment . . . 718
- Mercurial preservative . . . 740
- Mercuric chloride . . . 698, 744
- Mercurochrome . . . 615
- Mercurous chloride . . . 700
- Mercury . . . 565, 577, 674, 694, 698, 711, 740, 834
- Mercury bleach cream . . . 565
- Mercury compounds . . . 565
- Mercury preparations . . . 565
- Methyl bromide . . . 648
- Methyl salicylate . . . 577
- Metritis . . . 760
- Mild mercurial ointment . . . 718
- Milk
  - . dry skim . . . 398, 403, 742
  - . evaporated . . . 686, 710
  - . filled . . . 419
  - . grades of . . . 468
  - . malted . . . 685, 710
  - . sweetened condensed . . . 395, 710
- Milk, riboflavin in . . . 602
- Milk bread . . . 608, 710
- Milk fed poultry . . . 629
- Milk sherbet . . . 596, 710



- Mince pies . . . . 654  
Minced meat . . . . 654  
Mineral oil . . . . 56, 215, 575, 579, 681, 691,  
730, 735, 752, 757  
Mineral oil salad dressings . . . . 752  
Mineral properties, declaration . . . . 831  
Mineral water . . . . 2, 141, 187  
Minor violations . . . . 13, 179, 350, 829  
Mint tea . . . . 623  
Misbranded products  
    . cosmetic, when deemed to be . . . . 839  
    . device or drug, when deemed to  
      be . . . . 833, 834  
    . food, when deemed to be . . . . 831  
    . introduction into interstate commerce  
      prohibited . . . . 826  
    . manufacture in territory  
      prohibited . . . . 826  
Misbranding—See also "Misleading";  
    "Opinion evidence"  
    . adulteration distinguished . . . . 215  
    . proof of one charge sufficient . . . . 107,  
      197, 199, 299, 537, 560  
    . truthful label not sole test . . . . 115,  
      145, 419  
Misdemeanor, violation of Act . . . . 827  
Misleading—See also "Accompanying label-  
ing"; "Deceptive package"; "Fail-  
ure to reveal facts"; "False and  
misleading"; "Label"; "Labeling";  
"Misbranding"; "Strength, purity,  
and quality"  
    . ambiguous statements . . . . 2, 197, 199,  
      227, 299, 370, 526  
    . danger to health not in issue . . . . 5,  
      253, 299  
    . deterrent from seeking medical  
      advice . . . . 253, 299, 343, 529, 533  
    . failure to reveal presence of  
      poison . . . . 523  
    . half-truths . . . . 227, 370  
    . ingredients present in small  
      amounts . . . . 456, 526  
    . label and labeling read  
      together . . . . 274  
    . name of product . . . . 22, 89, 456, 526,  
      566  
    . naming of disease conditions . . . . 8, 64,  
      94, 218, 299  
    . proof of one charge sufficient . . . . 107,  
      197, 199, 299, 537, 560  
    . self-contradictory label . . . . 370  
    . similarity to another product . . . . 89,  
      135, 456  
    . to consumers . . . . 89, 94, 526  
    . trade name . . . . 456  
    . truthful labeling not sole test . . . . 419  
Misleading containers—See "Deceptive  
package"  
Mocha coffee . . . . 626  
Monition, accelerating return,  
    form . . . . 857  
Monochloroacetic acid . . . . 523, 721, 751  
Monosodium glutamate . . . . 660, 703, 762  
Moot question  
    . article destroyed . . . . 191  
    . labeling withdrawn does not  
      create . . . . 122  
Morphine . . . . 674, 834  
Morphine sulfate . . . . 659, 674, 746  
Motion for directed verdict—See  
    "Verdicts"  
Motion to dismiss . . . . 85, 110  
Motion to strike . . . . 454  
Motion to vacate default decree and order  
    form . . . . 861  
Motive—See "Intent"  
Motives of government . . . . 64  
Multiple seizures—See "Seizure"  
Munster cheese . . . . 678  
Muscle oil . . . . 567  
Mushrooms . . . . 191  
Mustard . . . . 577, 660  
Mustard bran . . . . 660  
  
N  
Nail grower . . . . 566  
Nails . . . . 631  
Name—See "Common or usual name";  
    "Food standards"; "Misleading"  
Name and place of business . . . . 831, 833,  
    839  
Name and quantity or  
    proportion . . . . 834, 845  
Name of another product—See  
    "Misleading"  
Name, quantity, and percentage . . . . 845  
Narcotics . . . . 659, 674, 688, 834  
National Formulary—See "Official  
    Compendium"  
Natural gum, in confectionery . . . . 830  
Nebulizer . . . . 742  
Needles . . . . 631  
Neoarsphenamine . . . . 719  
Neocinchophen . . . . 562, 633, 698, 708, 711,  
    713  
Net weight . . . . 629  
Neutralizer, in cream . . . . 636  
New and non-official remedies . . . . 602  
New drug  
    . application . . . . 436  
    . definition in Act . . . . 826  
    . use of representation as to effective  
      application prohibited . . . . 827  
New drug section, devices . . . . 614  
New drugs . . . . 436, 602, 608, 733, 759, 762,  
    835, 836  
    . animal use . . . . 759  
New trial, motion . . . . 303, 387  
Niacin . . . . 739  
Nicotinic acid . . . . 715  
Nipples . . . . 614  
Nitrogen, in canned foods . . . . 646  
Non-alcoholic carbonated  
    beverages . . . . 597, 710  
Non-allergic products . . . . 566  
Non-fat dry milk solids . . . . 398, 403  
Non-nutritive substance, confectionery  
    . . . . 830  
Noodles, egg . . . . 619, 634  
Nose drops . . . . 576  
    . sulfathiazole . . . . 733  
Nose sprays . . . . 576



Notice of hearing—See “Constitutionality”;  
“Food standards”; “Hearing be-  
fore prosecution”  
Notice of judgment, publication . . . 842  
Nourishing cream . . . 567  
Nunc pro tunc . . . 463  
Nutmeg extract . . . 569  
Nuts . . . 634, 685  
Nux vomica . . . 576, 675, 725, 744

## O

Obesity . . . 22, 34, 53, 107, 448  
Object of statute—See “Construction of  
Act”; “Purposes of Act”  
Occhi di bue . . . 583  
Offered for sale under name of other  
food . . . 831  
Official compendium . . . 833, 834  
    definition in Act . . . 825  
    National Formulary . . . 262, 359  
    U.S. Pharmacopoeia . . . 253, 262, 265,  
    833, 834  
Official drugs  
    designations . . . 618  
    exemptions . . . 618  
Official sample, portion to  
    claimant . . . 841  
Oil  
    anise . . . 569  
    baby . . . 585  
    bay . . . 584  
    bitter almonds . . . 569  
    blended edible . . . 676  
    cajeput . . . 684  
    cassia . . . 569  
    cassia cinnamon . . . 569  
    castor . . . 575  
    celery seed . . . 569  
    ceylon cinnamon . . . 569  
    chenopodium . . . 577, 698, 708, 713  
    cinnamon . . . 569  
    cloves . . . 569, 689  
    cod liver . . . 709  
    corn . . . 676  
    cubeb . . . 684  
    erigeron . . . 684  
    fish liver . . . 601, 645  
    lemon . . . 569  
    marjoram . . . 570  
    mineral . . . 56, 215, 575, 579, 681, 691,  
    730, 735, 752, 757  
    muscle . . . 567  
    nutmeg . . . 569  
    olive . . . 387, 585, 676, 684  
    orange . . . 569  
    pennyroyal . . . 684  
    peppermint . . . 569  
    petroleum, crude . . . 218, 270  
    Russian mineral . . . 681  
    savory . . . 569  
    spearmint . . . 570  
    star anise . . . 570  
    sweet basil . . . 570  
    tansy . . . 714  
    thyme . . . 570  
    turpentine . . . 577  
    vegetable . . . 568

Oil—continued  
    vitamin-carrying . . . 692  
    volatile . . . 576  
    wheat germ . . . 723  
    wintergreen . . . 570  
    wormseed . . . 714  
Oils . . . 564, 676, 684  
Ointment . . . 674, 694, 733, 743  
    antiseptic . . . 826  
    blue . . . 718  
Oleomargarine . . . 412, 710  
Oleoresin of ginger . . . 588  
Oleoresins . . . 576, 684  
Oleum myrciae . . . 584  
Olive oil . . . 387, 585, 676, 684  
Olives . . . 710  
Omissions from labeling—See “Failure to  
    reveal facts”  
Onions, flavor of . . . 619  
Opiates . . . 688  
Opinion evidence—See also “Evidence”  
    consensus of medical opinion . . . 227,  
    388  
    conflict of medical opinion . . . 34, 64,  
    94, 107, 197, 199, 299, 388, 496  
    hypothetical questions . . . 370  
    need not be based on precise  
    formula . . . 463  
    not obtainable by discovery . . . 482,  
    501  
    qualifications of expert . . . 270  
    statement of difference of  
    opinion . . . 826  
    weight for trier of facts . . . 2, 8, 197,  
    212, 253, 257, 299  
    where witness has not used  
    article . . . 8, 199, 227, 463,  
Opium . . . 834  
Opportunity to present views—See “Hear-  
    ing before prosecution”  
Optional ingredients . . . 830, 831  
Orange concentrate . . . 672  
Orange extract . . . 569, 710  
Orange flavor . . . 568, 639  
Orange juice . . . 672  
Orchic preparations . . . 721  
Orders  
    accelerating return of monition,  
    form . . . 857  
    exonerating bond, forms . . . 854, 855  
    permitting salvaging of condemned  
    product, form of . . . 850  
    permitting withdrawal of claim and  
    answer, form . . . 859  
    removing seizure action, form . . . 864,  
    865  
    vacating default decree, form . . . 861,  
    862, 863  
Ordinary individual . . . 831  
Organoleptic tests—See “Tests”  
Original package . . . 189  
Osteomyelitis . . . 760  
Otherwise unfit for food—See “Unfit for  
    food”  
Ouabain . . . 578, 834  
Ovarian extract . . . 574, 721



References are to page numbers.

Ovarian substances . . . 704, 721  
 Ovary . . . 574, 721  
 Ownership of seized article . . . 511  
 Oysters . . . 18, 129, 543, 673, 755  
   canned . . . 710, 755

## P

Package—See "Deceptive package"  
 Package form . . . 579, 653  
 Padang coffee . . . 626  
 Pamphlets—See "Labeling"  
 Pantothenic acid . . . 715, 738  
 Paper napkins . . . 585  
 Paper shields . . . 564  
 Para-aminobenzoic acid . . . 715, 734  
 Paraffin wax . . . 579  
 Paraldehyde . . . 834  
 Paraphenylenediamine . . . 149, 564  
 Paratoluyenediamine . . . 564  
 Parenteral solution of liver . . . 720  
 Pastina . . . 583  
 Pate de foie gras . . . 588  
 Peach blossom honey . . . 626  
 Peaches, canned . . . 648, 649, 656, 661  
 Peanut butter . . . 82, 641  
 Peanut butter sandwich . . . 666  
 Peanuts . . . 756  
 Pears, canned . . . 649, 656  
 Peas . . . 624, 673, 683, 695  
   canned . . . 289, 673, 683, 695  
 Peas and carrots . . . 672  
 Pectin . . . 657  
   confectionery containing . . . 830  
 Pediculosis pubis . . . 718  
 Penalties . . . 285, 294, 341, 348, 359, 827,  
   828  
 Penicillin . . . 834, 837, 838  
   veterinary use . . . 759  
 Penny candy . . . 670  
 Pennyroyal oil . . . 684  
 Pepper . . . 577, 660  
 Peppermint . . . 569  
 Peppermint extract . . . 569  
 Peppers, canned . . . 703  
 Perfume bottles . . . 593  
 Perfumes . . . 665  
 Perfumes, in cosmetics . . . 665  
 Peritonitis . . . 760  
 Permit control, emergency . . . 831, 832  
 Peroxide cream . . . 566  
 Person . . . 278  
   definition in Act . . . 825  
 Personam—See "Action in personam"  
 Perspiration . . . 581  
 Peruvian bonito . . . 758  
 Peruvian canned fish . . . 758  
 Petition for exoneration of bond,  
   forms . . . 854, 855  
 Petrolatum . . . 711  
 Petroleum oil . . . 218, 270  
 Peyote . . . 834  
 Pharmacists . . . 590, 591, 637  
 Pharmacopoeia—See "Homeopathic Pharm-  
   acopoeia"; "Official compendium"  
 Phenobarbital . . . 582  
 Phenol . . . 725, 741  
 Phenolphthalein . . . 575, 614

Phenylmercuric benzoate . . . 740  
 Phenylmercuric borate . . . 740  
 Philippine Islands . . . 666  
 Phosphides . . . 708, 713  
 Phosphoric acid . . . 618  
 Phosphorus . . . 708, 713  
 Physician, as pharmacists . . . 637  
 Pickles . . . 661  
 Pimento process cheese . . . 605  
 Pimentos, canned . . . 703  
 Pineal . . . 721  
 Pineapple preserves, imitation . . . 746  
 Pineapple products . . . 746  
 Pinto beans, canned . . . 635  
 Piperonal . . . 568  
 Pituitary preparations . . . 574, 687, 721  
 Pleadings—See "Indictment and informa-  
   tion"; "Libel"  
 Pneumonia, equine . . . 759  
 Poisonous ingredient, added — See also  
   "Added poisonous or deleterious  
   substance" . . . 759  
 Poisonous substance—See also "Added poi-  
   sonous or deleterious substance"  
   830, 832, 833, 838  
 Popcorn . . . 56  
 Poppy seeds . . . 78, 135, 477  
 Pore paste . . . 567  
 Pork and beans . . . 623  
 Post office fraud order . . . 5  
 Posterior pituitary extract . . . 687  
 Postponement Act . . . 845  
 Postponement regulation . . . 586  
 Potassium iodide . . . 702  
 Potassium metabisulfite . . . 736  
 Potassium nitrate . . . 707  
 Potassium tartrate . . . 8  
 Potato chips . . . 651  
 Potato sticks . . . 651  
 Potatoes, in sacks . . . 654  
 Potency—See "Strength, purity, and  
   quality"  
 Poultry . . . 620, 629, 630  
 Poultry preparations . . . 709  
 Powder containers . . . 592  
 Powder puffs . . . 592  
 Powdered ammonia . . . 588  
 Preliminary hearing—See "Hearing before  
   prosecution"  
 Prepared under insanitary conditions—See  
   also "Filth" . . . 830, 833, 838  
 Prescription legend—See also  
   "Prescriptions" . . . 834  
 Prescriptions . . . 319, 334, 350, 591, 637,  
   708, 713, 717, 741, 742, 835  
 Preservatives . . . 581, 582, 598, 636, 664,  
   681, 694, 698, 712, 725, 831  
 Preservatives, in drug solutions . . . 581  
 Preserves . . . 647, 710, 746  
 Preserving powders . . . 736  
 Presumption of regularity . . . 370, 398,  
   543  
 Pretzels . . . 660  
 Previous conviction . . . 348  
 Printed matter—See "Label"; "Labeling"  
 Private formula preparations . . . 614  
 Probable cause, for making multiple  
   seizures . . . 828



Probation, revocation . . . 507  
 Proceeding in rem—See "Action in rem"  
 Proceedings in name of United States . . . 829  
 Process cheese . . . 605, 662, 678, 704  
 Process cheese, pimento . . . 605  
 Processing of cosmetic in other establishment . . . 839  
 Processing of drug in other establishment . . . 835  
 Processing of food in other establishment . . . 832  
 Product of diseased or non-slaughtered animal . . . 830  
 Progrestational activities . . . 574, 721  
 Prophylactics . . . 173, 205, 330, 466, 471, 711, 731  
 Propylene glycol . . . 720, 727  
 Prosecution—See "Criminal procedure"; "Indictment and information"; "Hearing before prosecution"; "Verdicts"  
 Prostate . . . 721  
 Protective creams . . . 734  
 Prunes . . . 659  
 Psyllium seed . . . 696  
 Publicity . . . 842  
 Puerto Rico . . . 666  
 Pumpkin, yellow color . . . 654  
 Punishment for violation of Act . . . 827  
 Puntine . . . 583  
 Pure food . . . 589  
 Pure food color . . . 712  
 Pure fruit flavors . . . 625  
 Purified solution of liver . . . 720  
 Purity—See "Strength, purity, and quality"  
 Purports to be defined and standardized food—See also "Food standards" 831  
 Purports to be drug recognized in compendium . . . 834  
 Purposes of Act—See also "Construction of Act"  
     . . . prevent injury to public health  
         . . . Court of Appeals . . . 15, 129, 445  
         . . . District Court . . . 28, 34, 56, 173, 315, 319  
         . . . Supreme Court . . . 278  
     . . . to prevent illegal articles moving in interstate commerce  
         . . . Court of Appeals . . . 44, 85, 134  
         . . . District Court . . . 59  
         . . . Supreme Court . . . 249  
     . . . to protect public or consumer  
         . . . Court of Appeals . . . 44, 129, 135, 156, 285  
         . . . District Court . . . 59, 64, 78, 89, 94, 253, 265, 289, 299, 315, 319, 330, 348, 462, 473, 526, 529, 533  
         . . . Supreme Court . . . 249, 278, 350, 382  
     . . . to protect uninformed  
         . . . Court of Appeals . . . 227  
         . . . District Court . . . 34, 173, 523  
 Put-in syrups, canned fruits . . . 656  
 Putrid substance—See also "Filth" . . . 830, 833, 838  
 Pyelonephritis . . . 760  
 Pyridoxine . . . 715, 738  
 Pyroligneous acid . . . 623

## Q

Quality—See also "Strength, purity, and quality" standards . . . 830, 831  
 Quantity of contents . . . 580, 584, 590, 668, 831, 833, 839  
 Quantum of proof—See "Burden of proof"  
 Question of fact—See "Issue of fact"; "Responsibility"  
 Quinine . . . 89, 526, 577, 643, 707, 723, 733

## R

Radium . . . 708, 713  
 Raisin bread . . . 607, 710  
 Raspberry flavor . . . 655  
 Raw materials, food . . . 603  
 Raw sugar . . . 675  
 Razor blades . . . 613  
 Reasonable proximity—See "Removal"  
 Reasonable variations in cosmetic labels . . . 839  
 Reasonable variations in drug labels . . . 833  
 Reasonable variations in food labels . . . 831  
 Receipt and delivery . . . 334, 341  
 Receipt of contraband product and delivery prohibited . . . 826  
 Reconditioning—See "Release after condemnation"  
 Records of interstate shipment . . . 82, 126, 359, 379, 826, 841  
 Records of other agencies . . . 841  
 Rectal ointments . . . 743  
 Red pepper . . . 660, 703  
 Refined corn sugar . . . 567  
 Refusal to permit entry or inspection prohibited . . . 826  
 Refusal to permit inspection of records of interstate shipment prohibited . . . 826  
 Regularity—See "Presumption of regularity"  
 Regulations—See also "Administrator, Federal Security"; "Food standards" 839, 840  
     . . . authority to promulgate . . . 177, 839  
     . . . bulk shipments . . . 99  
     . . . collateral attack . . . 149, 161, 177, 289  
     . . . directions for use . . . 319, 533  
     . . . exemptions . . . 99, 319, 350  
     . . . interpretive, authorized . . . 34, 529, 533  
     . . . review . . . 177  
 Rejuvenating cream . . . 566  
 Relabeling—See "Bond for release"; "Condemnation and destruction"; "Release after condemnation"  
 Release after condemnation—See also "Bond for release"; "Condemnation and destruction" . . . 829  
     . . . administration determines method of reprocessing . . . 195, 496  
     . . . burden of reprocessing on claimant . . . 173, 480, 484, 490



References are to page numbers.

Release after condemnation—continued  
 . condemnation must precede  
   release . . . 26, 173, 179, 480  
 . court retains jurisdiction after  
   condemnation . . . 484  
 . denial of motion to permit  
   reprocessing . . . 222  
 . discretionary with court . . . 50, 195,  
   222, 227  
 . for export . . . 242, 513  
 . misbranded wholesome article may be  
   relabeled . . . 89, 162  
 . permitted for segregation . . . 173, 205  
 . proper relabeling immaterial in mis-  
   branding case . . . 5  
 Rem—See "Action in rem"  
 Removal—See also "Food standards"  
   828, 829  
 . based on adulteration . . . 119, 122  
 . district of reasonable  
   proximity . . . 1, 12, 21, 118, 154, 828  
 . forms . . . 864, 865  
 . grounds for refusing . . . 1, 12, 119  
 . multiple seizure . . . 119  
 . stipulation . . . 25  
 . subsequent order . . . 25, 58, 118  
 Renovated Butter Act . . . 156, 480  
 Repacking—See "Bulk shipments"; "Re-  
   lease after condemnation"  
 . product in other  
   establishment . . . 832, 835, 839  
 Representative sample . . . 179, 205, 829  
 Represented as standardized food . . . 831  
 Reprocessing—See also "Release after con-  
   demnation"  
 . condemned product . . . 829  
 Res—See "Articles"; "Action in rem"  
 Res adjudicata—See "Res judicata"  
 Residue—See "Spray residue"  
 Resins . . . 576  
 Resinous glaze, confectionery . . . 662,  
   830  
 Res judicata—See also "Federal Trade  
   Commission" . . . 80, 141, 182,  
   187, 389  
 Responsibility  
 . agents . . . 99, 278, 310  
 . corporations . . . 278  
 . parties . . . 99, 262, 278, 285, 341  
 . question of fact . . . 359, 388  
 Retail package . . . 629  
 Retail pharmacists . . . 590, 591  
 Retailers . . . 78, 319, 334, 350  
 Review of regulations . . . 177, 836, 840  
 Review on appeal—See "Appeal"; "Food  
   standards"  
 Rhubarb . . . 697  
 Riboflavin . . . 602, 715, 739  
 "Rock candy syrup" . . . 673  
 Rolls . . . 739  
 Roquefort cheese . . . 564  
 Rose extract . . . 569  
 Roughage material . . . 575  
 Royal Anne cherries, canned . . . 656  
 Rubber articles  
 . gloves . . . 585  
 . nipples . . . 614  
 . syringe . . . 613

Rubber articles—continued  
 . water bottle . . . 613  
 Rubbing alcohol . . . 650  
 Rubefacients . . . 577  
 Rules of Civil Procedure—See also  
   "Appeal" . . . 482, 501, 505, 521  
 Russian mineral oil . . . 681  
 Rye bread . . . 739  
 S  
 Saccharin . . . 691, 724, 726  
 Salad dressings . . . 597, 652, 689, 730, 752  
 Salad oils . . . 676, 696  
 Sale—See "Held for sale"; "Interstate  
   commerce"  
 Salicylic acid . . . 736  
 Salmon, canned . . . 652  
 "Salsa Di Pomodoro", tomato  
   paste . . . 628  
 Salt . . . 585, 676  
 . calcium . . . 752  
 Salted nuts . . . 685  
 Salt substitutes . . . 762  
 Salvaging—See "Release after condemna-  
   tion"  
 Samples  
 . condemnation of shipment based  
   on . . . 173, 179, 205  
 . failure to furnish . . . 294  
 . integrity . . . 370  
 . official sample, portion to  
   claimant . . . 841  
 . post-seizure . . . 205, 829  
 . representative . . . 179, 205, 829  
 . taking . . . 126, 359  
 Sandwich cuts . . . 630  
 Sanguinaria syrup . . . 643  
 Santonin . . . 577, 698, 708, 714  
 Saponin . . . 647  
 Sarda chilensis . . . 758  
 Sarda velox . . . 758  
 Sardines . . . 518  
 Sauerkraut . . . 710, 736  
 Sausage casing . . . 681  
 Sausage, chopped fish . . . 681  
 Savory extract . . . 569  
 Saws . . . 631  
 Scabies . . . 727, 730  
 Scalp food . . . 566  
 Scalp infections . . . 613  
 Scientific testimony—See "Opinion  
   evidence"  
 Scientific treatises—See "Evidence"  
 Scissors . . . 631  
 Scopolamine . . . 576  
 Screwdrivers . . . 631  
 Sea food, inspection . . . 841  
 Search and seizure—See "Constitutional-  
   ity"; "Factory inspection"; "Re-  
   cords of interstate shipment";  
   "Seizure"  
 Second offense—See "Previous conviction"  
 Secretary of Treasury . . . 496, 839, 842,  
   843  
 Segregation—See "Release after condemna-  
   tion"



- Seizure—See also “Action in rem”; “Admiralty in seizure actions”; “Constitutionality”; “Libel”; “Purpose of Act” . . . 828, 829
- at any time thereafter . . . 156, 210
  - civil action . . . 28, 34, 44
  - consolidation with injunction . . . 59
  - damages for breach of warranty not in issue . . . 511
  - from one's home . . . 207, 210, 226
  - imports . . . 238
  - limited number of actions . . . 12
  - multiple . . . 493, 828
  - time . . . 78, 135, 145
  - title of article in issue . . . 511
- Self-diagnosis—See “Lay users”; “Self-medication”
- Self-medication—See also “Lay users” . . . 34, 107, 207, 210, 343, 448, 533
- Senna . . . 697
- Separability clause . . . 843
- Separation—See “Release after condemnation”
- Shampoo . . . 625
- Shampoo tints . . . 666
- Shaving brushes . . . 612
- Shaving cream . . . 625
- Shell fragments . . . 18
- Shellac, confectionary . . . 662
- Shelled peanuts . . . 756
- Sherbets . . . 596, 599, 710
- Sherley Amendment . . . 64
- Shipment—See “Article”; “Bulk shipments”; “Condemnation and Destruction”; “Interstate commerce”; “Records of interstate shipment”
- Shipping package . . . 667
- Shortening ingredients, declaration . . . 607
- Shortenings . . . 594, 610, 651
- Shrinkage . . . 830
- Shrimp, canned . . . 652, 710
- Silver dragees, cake decoration . . . 663
- Silver hake . . . 670
- Silver preparations . . . 577
- Similarity of products—See “Misleading”
- Skim milk . . . 398, 403, 742
- Skim Milk Act . . . 848
- Skin diseases . . . 218, 270
- Skin preparation . . . 567
- conditioner . . . 567
  - firm . . . 567
  - food . . . 567
  - texture preparations . . . 567
  - tonic . . . 567
- Skipjack . . . 758
- Slack fill—See also “Deceptive package”; “Standard of fill” . . . 193, 568, 632
- Small packages . . . 831, 833, 839
- Smoke, substitute . . . 623
- Soap . . . 585, 625, 675
- Soap, medicinal . . . 675
- Soda tablet . . . 700
- Sodium benzoate . . . 598, 736
- Sodium bisulphite . . . 664, 694
- Sodium bromide . . . 687
- Sodium cacodylate . . . 674
- Sodium carbonate . . . 660
- Sodium chloride . . . 746
- Sodium diet . . . 762
- Sodium dimethylarsenate . . . 674
- Sodium glutamate . . . 703
- Sodium nitrite, fish fillets . . . 652
- Sodium penicillin, veterinary use . . . 759
- Sodium perborate . . . 576, 658
- Soft drink powders . . . 655
- Solid pack peaches . . . 661
- Solution of liver . . . 720
- Solutions . . . 745
- Soups, canned . . . 686
- Soybean flour, addition of carotene . . . 645
- Spaghetti . . . 189, 583
- Spaghettini . . . 583
- Spearmint . . . 570
- Spearmint extract . . . 570
- Special dietary uses, food . . . 831
- Specially denatured alcohol . . . 623
- Spice flavorings . . . 689
- Spices . . . 689, 831
- Spinach, unfit . . . 514
- Spiritus myrciae compositus . . . 584
- Sprats . . . 582
- Spray residue . . . 440
- Sprays, nose . . . 576
- Squalene . . . 387
- Squill . . . 578, 698, 713
- Standard of fill—See also “Deceptive package”; “Slackfill” . . . 830, 831
- Standard of identity—See “Food standards”
- Staphylococci . . . 759
- Star anise extract . . . 570
- Starches . . . 652, 689, 705
- Starches, salad dressings . . . 652
- State laws—See “Jurisdiction”
- State officials, examinations and investigations by . . . 841
- Statement of policy . . . 543
- Statutory construction—See also “Construction of Act”; “Purposes of Act”
- Act construed as a whole . . . 533
  - criminal laws . . . 382, 443
  - implied repeal . . . 156
  - inconsistent statutes . . . 156
  - meaning of words . . . 405
  - sections of Act are
    - independent . . . 412
    - singular applied to several things . . . 398
- Stearic acid, confectionery . . . 662
- Stelline . . . 583
- Sterilization . . . 687
- Sterilized toilet articles . . . 612
- Stimulating cream . . . 566
- Stipulation consolidating and removing seizure actions, forms . . . 864, 865
- Stipulation of facts . . . 303, 443
- Storage expenses . . . 829
- Strained honey . . . 686
- Strained tomatoes . . . 627
- Stramonium . . . 717, 743
- Stramonium alkaloid . . . 716



References are to page numbers.

- Strangles of horses . . . 759, 760  
 Strawberry flavor . . . 618, 655  
 Strawberry jam, imitation . . . 712  
 Strength, purity and quality—See also  
     "Misleading"  
     as affecting food standards . . . 412  
     devices, failure to comply with  
         represented . . . 173  
     drugs  
         failure to comply with  
             represented . . . 285  
         failure to comply with official  
             compendium . . . 253, 265  
 Streptococci . . . 759  
 Streptococcus agalactiae . . . 759, 760  
 Streptococcus agalactiae mastitis . . . 759,  
     761  
 Streptococcus dysgalactiae . . . 759, 760  
 Streptococcus uberis . . . 759, 760  
 Streptomycin . . . 834, 837, 838  
 Strophanthin . . . 834  
 Strophanthus . . . 578, 633, 698, 714  
 Strychnine . . . 576, 674, 675, 714, 741, 743,  
     834  
 Strychnine sulfate . . . 674, 744  
 Sturgeon caviar . . . 651  
 Subpoenas . . . 829  
 Substandard legend . . . 831  
 Substantial evidence—See "Evidence";  
     "Food standards"  
 Substitution—See also "Economic adultera-  
     tion"; "Misleading" . . . 830, 833  
 Sugar—See also "Sweetening  
     ingredients" . . . 724  
     barley . . . 584  
     beans with pork . . . 621  
     corn . . . 567  
     ingredient of flavors . . . 618  
     invert . . . 682  
     raw . . . 675  
 Sugar candy, barley . . . 584  
 Sugar cane syrup . . . 673  
 Sugar syrup . . . 649, 682  
 Sulfa drugs—See "Sulfanilamides"  
 Sulfanilamide veterinary . . . 716, 719  
 Sulfanilamides . . . 561, 562, 633, 641, 643,  
     698, 708, 713, 716, 717, 719, 734  
 Sulfapyradine . . . 698, 708, 713  
 Sulfathiazole . . . 319, 334, 350, 708, 713, 733  
 Sulfites . . . 736  
 Sulfonamide ointment . . . 733  
 Sulfonamides . . . 741  
 Sulfur . . . 727  
 Sulfur dioxide . . . 736  
 Sulphonmethane . . . 834  
 Sumatra coffee . . . 626  
 Sunburn preparations . . . 593  
 Sun-screen lotions . . . 734  
 Sun tan preparations . . . 593  
 Superior brand . . . 732  
 Supporters . . . 611  
 Suprarenal preparations . . . 574, 721  
 Supreme quality . . . 686  
 Surface application . . . 574  
 Surgical instruments . . . 631  
 Surgical rubber gloves . . . 585  
 Surgical sutures, certified color . . . 619  
 Suspensory bandages . . . 611  
 Sutures . . . 619  
 Swedish anchovies . . . 582  
 Swedish rye bread . . . 606  
 Sweet basil . . . 570  
 Sweet chocolate . . . 710  
 Sweet marjoram extract . . . 570  
 Sweet milk chocolate . . . 710  
 Sweet potatoes, canned . . . 697  
 Sweetened condensed milk . . . 395, 710  
 Sweetening ingredients . . . 395, 431  
 Swine erysipelas . . . 759, 760  
 Swiss cheese . . . 630, 678  
 Swordfish, frozen . . . 639  
 Synthetic aldehydes . . . 681  
 Synthetic esters . . . 681  
 Synthetic flavors . . . 618, 681  
 Synthetic ketones . . . 681  
 Syphilis—See also "Prophylac-  
     tics" . . . 711, 731  
 Syringe . . . 613  
 Syrup of hypophosphites . . . 643  
 Syrups—See also "Sweetening  
     ingredients" . . . 568  
     cane and maple . . . 669  
     invert sugar . . . 682  
     malt . . . 657  
     packing . . . 649, 656  
     rock candy . . . 673  

T

 Table cream . . . 706  
 Tablet compressing operations . . . 611  
 Tablets, colored . . . 659  
 Tan . . . 565  
 Tansy . . . 714  
 Tansy oil . . . 714  
 Tapeworm, in poultry . . . 620  
 Tartar emetic . . . 643  
 Tartaric acid . . . 618  
 Tea, Kentucky mint . . . 623  
 Tea bags . . . 609  
 Technical use . . . 614  
 Telephone peas . . . 683  
 Terpeneless extract of lemon . . . 568  
 Terpeneless extract of orange . . . 568  
 Terpeneless oil of lemon . . . 568  
 Terpeneless oil of orange . . . 568  
 Territory . . . 825, 826  
 Testimonials—See "Evidence"  
 Tests  
     clinical studies . . . 64, 227  
     experiments . . . 227  
     methods, in general . . . 59  
     mold as showing filth . . . 449  
     organoleptic . . . 48, 110, 129, 179, 257,  
         526  
     rendering article useless . . . 173  
     squalene . . . 387  
 Tetanus . . . 759, 760  
 Tetrachlorethylene . . . 576, 698, 708, 714  
 Therapeutic devices . . . 631  
 Thermometers . . . 693  
 Thiamine—See also "Vitamins" . . . 715,  
     739  
 Thiocyanates . . . 708, 714  
 Thiouracil . . . 759  
 Thunnus macropterus . . . 758



Thyme extract . . . 570  
 Thymol . . . 577, 698, 708, 714  
 Thyroid . . . 22, 34, 107, 370, 448, 698, 708, 714, 834  
 Tilsit cheese . . . 678  
 Time of adulteration—See "Adulteration"  
 Time of seizure—See "Seizure"  
 Tincture of arnica . . . 587, 588  
 Tincture of iodine . . . 609  
 Tincture strophanthus . . . 633  
 Tint, eyebrow . . . 149, 159, 161, 177  
 Tissue cream . . . 567  
 Tissue paper wrappers . . . 680  
 Titanium dioxide . . . 581  
 Title  
   issue in seizure action . . . 511, 514  
   passing . . . 85, 99  
 Title of Act . . . 825  
 Toilet articles . . . 612  
 Toilet water . . . 665  
 Tolerance—See also "Decomposed substance"; "Filth"  
   Act supersedes regulation granting . . . 179  
   added substance . . . 18, 832  
   fungus in sardines . . . 518  
   none for defects in shipment . . . 173  
   none for filth . . . 179, 222, 451  
   spray residue . . . 440  
 "Tolu and codeine" . . . 643  
 Tomato catsup—See also "Catsup" . . . 145, 637  
 Tomato hot sauce . . . 690  
 Tomato juice . . . 162, 225, 592, 627, 637, 680  
 Tomato juice, with chili juice . . . 612  
 Tomato juice cocktail . . . 612  
 Tomato paste . . . 13, 627, 628, 637, 640, 688  
 Tomato products, artificial color . . . 637  
 Tomato puree . . . 44, 179, 627, 637, 640, 683, 690  
 Tomato puree, imitation . . . 627  
 Tomato sauce . . . 162  
   with beans and pork . . . 621  
 Tomatoes . . . 627, 683, 688  
   canned . . . 592, 627, 688  
 Tongue depressors . . . 609  
 Tonic, hair . . . 655, 707  
 Tonics . . . 655, 741, 743  
 Tonka bean . . . 570  
 Tonka extract . . . 570  
 Tooth brushes . . . 612  
 Tooth powder . . . 659  
 Totaquine . . . 733  
 Trade name . . . 582, 668  
 Trade secret, revealing of information acquired under Act prohibited . . . 827  
 Transfer—See "Removal"  
 Treasury—See "Secretary of Treasury"  
 Treatises—See "Evidence"  
 True fruit flavors . . . 611  
 Tuna, canned . . . 652, 734, 758  
 Turpentine oil . . . 577

## U

Unattractiveness—See "Filth"  
 Undrawn poultry . . . 629  
 Unfit for food—See also "Adulteration"; "Decomposed substance"; "Filth" . . . 830  
   article, need not be decomposed or filthy . . . 13, 59, 179  
 United States, proceedings in name . . . 829  
 United States Pharmacopoeia . . . 253, 262, 265, 833, 834  
 Universal . . . 716  
 Unmixed canned fruits . . . 710  
 Unmixed canned vegetables . . . 710  
 Unsafe . . . 310, 830, 832, 833, 834, 835, 837, 838  
 Unsafe dosage or methods or duration of administration or application . . . 834  
 Unsaturated fatty acids . . . 611  
 Until relieved . . . 680  
 Unwrapped bakery products . . . 634  
   bread . . . 634  
   cake . . . 634  
   pie . . . 634  
 Urinary tract . . . 576  
 U. S. Grade A . . . 603  
 Users—See "Lay users"  
 Usual name—See "Common or usual name"  
 Uva ursi . . . 707

## V

Validity of regulations—See "Food standards"; "Regulations"  
 Valuable constituent, omission of in food . . . 830  
 Vanilla bean . . . 570  
 Vanilla extract . . . 570, 710  
 Vanilla flavor . . . 568, 639, 677  
 Vanilla ice cream . . . 600  
 Vanilla oleoresin . . . 568  
 Vanilla solution . . . 568  
 Vanilla wafers . . . 677  
 Vanillin . . . 568, 600, 618, 638  
 Vanillin and coumarin flavor . . . 568  
 Vanity cases . . . 593  
 "Vegetable", laxatives . . . 580  
 Vegetable colors . . . 702  
 Vegetable oils . . . 568  
 Vegetable shortenings . . . 594  
   potato chips . . . 651  
 Vegetables  
   canned . . . 686, 710  
   dried . . . 830  
   fresh . . . 658, 677, 830, 832  
   wrappings . . . 680  
 Venereal disease—See also "Prophylactics" . . . 711, 731  
 Venue—See "Removal"  
 Verdicts—See also "Criminal procedure"  
   authority to set aside . . . 387  
   inconsistency of . . . 262, 278  
   motion for directed . . . 387  
   separate, as to each defendant . . . 359, 388



## Index

References are to page numbers.

Verdicts—continued  
     . separate, on each count . . . 359, 388  
     . special, in criminal cases . . . 537  
     . special, in seizure cases . . . 197  
     . surplusage . . . 537  
 Verification of libel—See "Libel"  
 Vermicelli . . . 583  
 Veterinary products . . . 604, 620, 716,  
     719, 729, 731, 759, 760  
 Vignettes, use on labels . . . 652  
 Vinegar . . . 589, 590, 695, 736  
 Violations—See "Minor Violations"  
 Virgin Islands . . . 666  
 Virus, Serum, and Toxin Act . . . 844  
 Viruses . . . 759  
 Vitamin capsules . . . 601, 726  
 Vitamin-carrying oil . . . 692  
 Vitamins . . . 601, 602, 611, 645, 692, 709,  
     715, 723, 725, 736, 737, 738, 742  
     . enriched foods . . . 405, 419  
     . food or drug . . . 265  
     . in general . . . 285, 343  
 Vitamins, expressing content in  
     foods . . . 607, 831  
 Volatile oils . . . 576

## W

Wafers  
     . butter . . . 607  
     . vanilla . . . 677  
 Warnings . . . 94, 562, 563, 574, 591, 604,  
     690, 714, 744, 752, 834  
 Warrant, breach of—See "Condemnation";  
     "Damages"; "Jurisdiction"  
 Water—See "Distilled water"; "Mineral  
     water"  
 Water, ingredient of flavor . . . 618  
 Water ice . . . 596, 710  
 Weight, measure, or numerical  
     count . . . 831, 833, 839  
 West Indian bay rum . . . 738  
 Wet dressing, antiseptic . . . 826  
 Wheat . . . 496  
 Wheat bread . . . 739

Wheat germ oil . . . 723  
 Whipping cream . . . 706  
 White bread . . . 607, 710, 739  
 White pine bark . . . 587  
 Whitefish caviar . . . 651  
 Whiting . . . 670  
 Whiting fillets . . . 670  
 Whole eggs . . . 578  
 Whole wheat bread . . . 607, 710  
 Wild cherry bark . . . 587  
 Wine base . . . 725  
 Wintergreen extract . . . 570  
 Withdrawal of claim and answer,  
     form . . . 859  
 Witnesses—See "Appeal"; "Discovery";  
     "Evidence"; "Lay users";  
     "Opinion evidence"  
 Wooden applicators . . . 609  
 Worm powder . . . 274  
 Wormseed oil . . . 714  
 Wrapped fillets . . . 670  
 Wrapped fish . . . 670  
 Wrapped Meats Act . . . 843, 847  
 Wrappers . . . 680  
 Wrinkle eradicator . . . 567  
 Wrist bands, elastic . . . 611

## X

X-ray machines . . . 633, 700

## Y

Yam . . . 697  
 Yeast nutrient . . . 607  
 Yeast tablets . . . 738  
 Yellow phenolphthalein . . . 614  
 Yellowfin . . . 758  
 Yemen, coffee . . . 626

## Z

Zinc oxide ointment . . . 674  
 Zucca melon . . . 680  
 Zufolini . . . 583











C. F. T. R. I. LIBRARY, MYSORE.

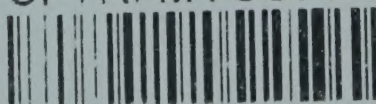
Acc. No. 1078

Call No. ~~F85, 3-OL: (Z73)~~ H9  
F8, 3: (Z) N49 ← N38

Please return this publication on or before the last DUE DATE stamped below to avoid incurring overdue charges.

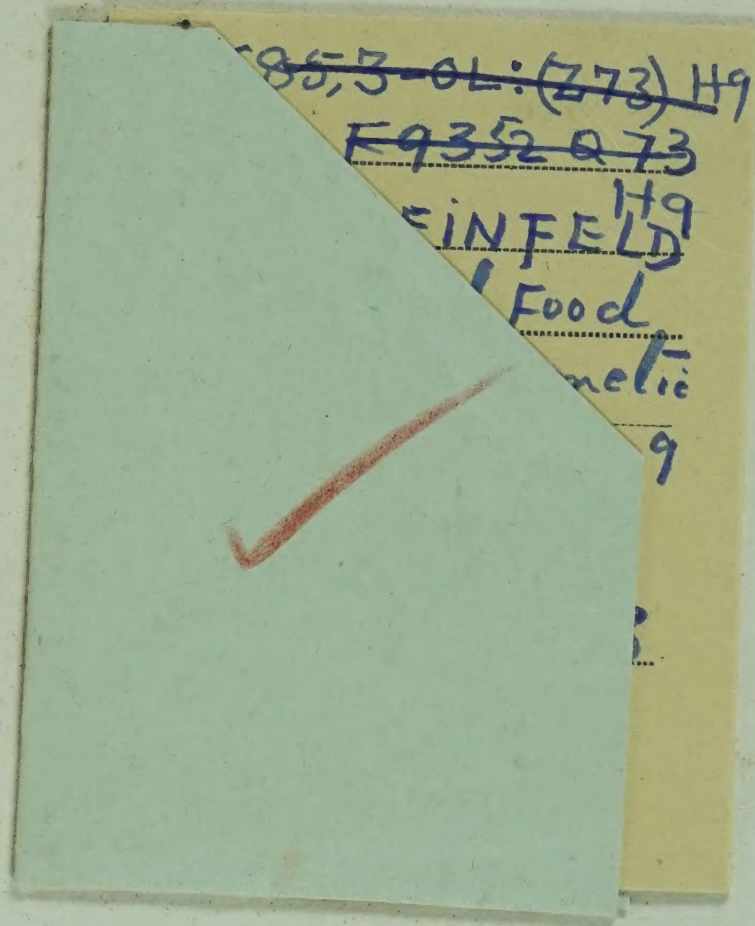
Due Date	Return Date	Due Date	Return Date	Due Date	Return Date
4-177					

CFTRI-MYSORE



1078  
Federal food dr.





~~85,3-OL:(273) H9~~

~~F9352 Q73~~

H9  
FINFELD

Food

netic

9



